

OMEROS CORP  
Form 10-K  
March 18, 2013  
[Table of Contents](#)

**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, 2012**

**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)

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

# Edgar Filing: OMEROS CORP - Form 10-K

of incorporation or organization)  
201 Elliott Avenue West

Identification Number)

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 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 ☐ Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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 \$202,573,390. Shares of voting stock held by each officer and director and by each person who, to the registrant's knowledge, owns 5% or more of the outstanding voting stock (as publicly reported by such persons pursuant to Section 13 and Section 16 of the Securities Exchange Act of 1934) have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 13, 2013, 25,910,399 shares of the registrant's common stock were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Specified portions of the registrant's proxy statement with respect to the 2013 Annual Meeting of Shareholders to be held May 24, 2013, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2012, are incorporated by reference into Part III of this Form 10-K.

**Table of Contents**

**OMEROS CORPORATION**

**ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2012**

**INDEX**

	<b>Page</b>
<b><u>PART I</u></b>	
ITEM 1. <u>BUSINESS</u>	1
ITEM 1A. <u>RISK FACTORS</u>	23
ITEM 1B. <u>UNRESOLVED STAFF COMMENTS</u>	43
ITEM 2. <u>PROPERTIES</u>	43
ITEM 3. <u>LEGAL PROCEEDINGS</u>	44
ITEM 4. <u>MINE SAFETY DISCLOSURES</u>	44
<b><u>PART II</u></b>	
ITEM 5. <u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	45
ITEM 6. <u>SELECTED CONSOLIDATED FINANCIAL DATA</u>	47
ITEM 7. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	48
ITEM 7A. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	59
ITEM 8. <u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	59
ITEM 9. <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	59
ITEM 9A. <u>CONTROLS AND PROCEDURES</u>	59
ITEM 9B. <u>OTHER INFORMATION</u>	62
<b><u>PART III</u></b>	
ITEM 10. <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	63
ITEM 11. <u>EXECUTIVE COMPENSATION</u>	63
ITEM 12. <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS</u>	63
ITEM 13. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	63
ITEM 14. <u>PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	64
<b><u>PART IV</u></b>	
ITEM 15. <u>EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	65
<u>SIGNATURES</u>	66

**Table of Contents**

**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 facts are forward-looking statements for purposes of these provisions. In some cases you can identify forward-looking statements by terms such as may, will, should, could, would, expect, plan, anticipate, believe, estimate, project, predict, and potential. We intend to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding:

our ability to submit a New Drug Application and a Marketing Authorization Application for OMS302 during 2013 and to subsequently receive regulatory approval for the commercialization of OMS302 in 2014;

our ability to commence a second Phase 3 clinical trial for OMS103HP during the first half of 2013;

our ability to submit an Investigational New Drug application and/or Clinical Trial Application, and initiate clinical trials, for both OMS721 and OMS527 in 2013;

our ability to raise capital under our at-the-market equity facility with MLV & Co. LLC, committed equity line financing facility with Azimuth Opportunity, Ltd. or to otherwise access the capital markets;

our expectations regarding the clinical benefits of our products;

our expectation that the clinical benefits of our products could provide surgeons a competitive marketing advantage and facilitate third-party payor acceptance;

whether the variant KD1 proteins we are developing in our Plasmin program could provide more effective bleeding control with fewer side effects Trasylol®;

our ability to obtain commercial supplies of our PharmacoSurgery® products, our competition and, if approved, our ability to successfully commercialize our PharmacoSurgery products with a limited, hospital-based marketing and sales force;

our expectation that 2014 is the earliest year 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;

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 sales and marketing plans for our products and programs, including OMS302 and OMS103HP;

our expectations about the commercial competition that our products may face;

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 expected financial position, performance, growth, expenses, the magnitude of our net losses and the availability of resources;

our involvement in potential claims and legal proceedings, the expected course and costs of existing claims and legal proceedings, and the potential outcomes and effects of both existing and potential claims and legal proceedings on our business, prospects, financial condition and results of operations;

our plans to file additional patent applications to enhance and protect our existing intellectual property portfolio; 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 1A of this Annual Report on

**Table of Contents**

Form 10-K under the heading “Risk Factors” and in our other filings with the SEC. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our management’s 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 future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

**Table of Contents****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 products are 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 preemptively inhibit inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. We currently have five clinical-stage development programs. In addition, we have a deep and diverse pipeline of preclinical programs as well as a platform capable of unlocking new drug targets. 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:

		Targeted		Next Expected	Worldwide
Program		Procedure/Disease	Development Status	Milestone	Rights
<b>Clinical Programs</b>					
OMS302	Ophthalmology	Intraocular Lens Replacement Surgery	NDA	Submit New Drug Application (NDA)	Omeros
OMS103HP	Arthroscopy	Arthroscopic Meniscectomy	Phase 3	Begin Second Phase 3 Trial	Omeros
OMS201	Urology	Ureteroscopy	Phase 1/2	Design Phase 2 Trial	Omeros
PDE10 (OMS824)		Schizophrenia, Cognitive Disorders and Huntington's Disease	Phase 1	Complete Phase 1 Trial	Omeros
PPARg (OMS405)		Opioid, Nicotine and Alcohol Addiction	Phase 2	Complete Phase 2 Trials	Omeros
<b>Preclinical Programs</b>					
MASP-2 (OMS721)		aHUS, PNH, AMD, Transplant, Ischemia Reperfusion Injury	Preclinical	Initiate Phase 1 Trial	Omeros (In-licensed)
PDE7 (OMS527)		Addictions and Compulsive Disorders; Movement Disorders	Preclinical	Initiate Phase 1 Trial	Omeros (Compounds In-licensed)
Plasmin (OMS616)		Surgical and Traumatic Bleeding	Preclinical	Initiate Phase 1 Trial	Omeros (In-licensed)
<b>GPCR Program</b>		Multiple Disorders	Platform	Continue Drug Discovery for Class A Orphan and Class B GPCRs	Omeros



## **Table of Contents**

### **Clinical Programs**

#### ***PharmacoSurgery Platform***

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, 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, 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 preemptively block the molecular-signaling and biochemical cascade caused by surgical trauma and to provide clinical benefits both during and after surgery. Supplied in pre-dosed, pre-formulated, single-use containers, our PharmacoSurgery products are added to standard surgical irrigation solutions and delivered intraoperatively to the site of tissue trauma throughout the surgical procedure. This results 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 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, and are eligible for submission under the potentially less-costly and time-consuming Section 505(b)(2) New Drug Application, or NDA, process.

#### ***OMS302 Ophthalmology***

*Background.* OMS302 is our product being developed for use during intraocular lens replacement, or ILR, surgery, including cataract and other lens replacement surgery. OMS302 is a proprietary combination of ketorolac, an anti-inflammatory API, and phenylephrine, a mydriatic API. FDA-approved drugs containing each of these APIs have been used in ophthalmological clinical practice for more than 15 years, and both APIs are contained in generic, FDA-approved drugs.

Cataract and other lens replacement surgery involves replacement of the original lens of the eye with an artificial intraocular lens. These procedures are typically performed to replace a lens opacified by a cataract or to correct a refractive error of the lens. OMS302 is added to standard irrigation solution used in ILR surgery and delivered intracamerally to maintain intraoperative mydriasis (pupil dilation), to prevent surgically induced miosis (pupil constriction), and to reduce postoperative pain and irritation. Mydriasis is essential for these procedures and, if not maintained throughout the surgical procedure or if miosis occurs, risk of damaging structures within the eye increases as does the operating time required to perform the procedure.

*Clinical Trial Results.* OMS302 has been evaluated in Phase 1/Phase 2, Phase 2b and Phase 3 clinical trials in patients undergoing cataract extraction and lens replacement procedures and refractive lens exchange. In the double-blind Phase 1/Phase 2 clinical trial, 61 patients were randomized to receive one of three treatments: (1) OMS302, (2) phenylephrine alone, or (3) vehicle control. Patients were monitored for intraoperative pupil diameter and postoperative pain and inflammation for 14 days. Although this was an exploratory trial, patients

## **Table of Contents**

treated with either OMS302 or phenylephrine demonstrated statistically significant improvement in maintenance of mydriasis compared to patients treated with vehicle control. OMS302-treated patients reported less postoperative pain than patients treated with either phenylephrine or vehicle control. OMS302 was well tolerated with no serious adverse events and no discontinuations due to adverse events. The type and number of adverse events were similar across all treatment groups.

The Phase 2b clinical trial was a multicenter, randomized, double-blind, vehicle-controlled clinical trial 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 OMS302, the second arm (n=55) received only phenylephrine, the third arm (n=54) received only ketorolac and the fourth arm (n=57) received standard irrigation solution without drug. The co-primary endpoints of the trial included maintenance of mydriasis and reduction of postoperative ocular pain. The OMS302 group demonstrated statistically significant maintenance of mydriasis over both ketorolac- ( $p < 0.0001$ ) and vehicle-treated ( $p < 0.0001$ ) groups. OMS302 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 OMS302-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 analyses are intent-to-treat. These results demonstrate that each component of OMS302 contributed to the efficacy of the product, with both phenylephrine and ketorolac additively providing intraoperative mydriasis and ketorolac alone responsible for postoperative pain reduction. OMS302 was well tolerated in this trial.

We have completed two pivotal Phase 3 clinical trials that evaluated OMS302. Each of these trials was a multicenter, double-blind, placebo-controlled clinical trial that included over 400 patients randomized 1:1 to receive either OMS302 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, OMS302 demonstrated statistically significant ( $p < 0.00001$  in both trials) 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, OMS302 achieved p values of less than 0.05 in a series of other clinically relevant measures. In each Phase 3 clinical trial, OMS302 was well-tolerated. The most common adverse events were those related to surgery, specifically eye pain, eye inflammation, headache and increased intraocular pressure. The incidence of these adverse events was similar between OMS302- and placebo-treated patients.

*Commercialization Plan.* We are now preparing to submit an NDA to the FDA during the first half of 2013 and a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, in mid-2013 to allow us to market and sell OMS302 in the United States and the European Union, respectively. Assuming approval of at least one of these marketing applications within approximately one year of its submission, we expect to begin marketing OMS302 in 2014. Although the positive results from the OMS302 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 OMS302 in 2014 or ever.

### *OMS103HP Arthroscopy*

*Background.* OMS103HP is our PharmacoSurgery product being developed for use during arthroscopic procedures, including partial meniscectomy surgery, and was designed to provide a multimodal approach to preemptively block the inflammatory cascade induced by arthroscopy. OMS103HP is a proprietary combination of anti-inflammatory/analgesic APIs, 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 United States as over-the-counter, or OTC, or prescription drug products for over 15 years and have established and well-characterized safety profiles.

## **Table of Contents**

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 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 in performing arthroscopic procedures is adequately controlling the local inflammatory response to surgical trauma, particularly the pain and swelling that lead to restricted joint motion and loss of function. Added to standard irrigation solutions, OMS103HP 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 OMS103HP 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 OMS103HP and 72 vehicle). 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 OMS103HP and 34 vehicle).

In this study, OMS103HP 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. OMS103HP 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, OMS103HP, 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 OMS103HP to vehicle control in 344 patients undergoing arthroscopic partial meniscectomy surgery. The pre-specified primary endpoint was the Symptoms Subscale of the 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, OMS103HP 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. OMS103HP also demonstrated improvement across a series of pain-related assessments including postoperative narcotic usage (with more than twice as many OMS103HP-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, OMS103HP was well tolerated.

Although the positive results from our Phase 2 and Phase 3 clinical trials evaluating OMS103HP are encouraging, there can be no assurance that they will be predictive of the results obtained from later trials.

*Development Plan.* OMS103HP is in a Phase 3 program evaluating the product's safety and ability to reduce early postoperative pain following arthroscopic partial meniscectomy surgery. We expect to conduct two more Phase 3 clinical trials with reduction of early postoperative pain as the pre-specified primary endpoint and to begin enrolling patients in the first of these two planned trials in the first half of 2013. Each of these two additional Phase 3 clinical trials are expected to enroll substantially fewer subjects than were required for the first Phase 3 trial assessing KOOS as the primary endpoint given the increased statistical power associated with reduction in early postoperative pain shown in the Phase 2 and first Phase 3 meniscectomy clinical trials.

## **Table of Contents**

*ACL Reconstruction Program.* In the first quarter of 2011, we announced that OMS103HP failed to meet pre-specified efficacy endpoints in a Phase 3 clinical program in patients undergoing arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery. We were unable to draw any conclusions about OMS103HP's effect in the Phase 3 ACL program due to confounding factors, and we have no plans to conduct additional ACL reconstruction trials at this time.

### *OMS201 Urology*

*Background.* 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 during urological procedures. Both of the APIs in OMS201 are contained in generic, FDA-approved drugs that have been marketed in the United States for more than 15 years and have well-known profiles of safety and pharmacologic activities. 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 being developed 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. There were no deaths or discontinuations for adverse events. Only one serious adverse event was reported, which occurred in a vehicle-treated patient.

*Development Plan.* The next step in our OMS201 program is to design a Phase 2 clinical program. As our clinical development efforts are currently focused on our other programs, we are not conducting any activities in the OMS201 program at this time and do not expect to do so during 2013, but expect that we will resume the OMS201 program when we have adequate resources to devote to this program.

### *PDE10 Program OMS824*

*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. Our proprietary compound OMS824 inhibits PDE10 and is being developed for the treatment of cognitive disorders, including schizophrenia where OMS824 may have a beneficial effect on the positive (e.g., hallucinations), negative (e.g., flat affect) and cognitive symptoms of the disease. In multiple animal models of psychotic behavior, PDE10 inhibitors have been shown to be as effective as current anti-psychotic drugs. In addition, results from preclinical studies suggest that PDE10 inhibitors may address the limitations of currently used anti-psychotic drugs by avoiding the associated weight gain, improving cognition and, potentially, reducing the risk of associated sudden cardiac death.

*Clinical Trial Results.* We are currently conducting a Phase 1 clinical trial evaluating OMS824's safety, tolerability and pharmacokinetics in healthy subjects. This clinical trial includes a single ascending dose, or SAD,

## **Table of Contents**

study and a multiple ascending dose, or MAD, study. In the SAD study, 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.

*Funding Agreement with The Stanley Medical Research Institute.* Our preclinical development 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. The funding agreement and our obligation to pay a royalty to SMRI terminate when we have repaid such amount in the form of royalties.

### ***PPARg Program OMS405***

*Overview.* In our peroxisome proliferator-activated receptor gamma, or PPARg, program, we are developing proprietary compositions that include PPARg 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 PPARg and addiction disorders. Data from European pilot clinical studies and animal models of addiction suggest that PPARg agonists could be efficacious in the treatment of a wide range of addictions. Our collaborators at The New York State Psychiatric Institute are conducting two Phase 2 clinical trials for our PPARg program. These studies are evaluating a PPARg 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 will have the right 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 PPARg program.

*Patent Assignment Agreement with Roberto Ciccocioppo, Ph.D.* We acquired the patent applications and related intellectual property rights for our PPARg program in February 2009 from Roberto Ciccocioppo, Ph.D. of the Università di Camerino, Italy, pursuant to a patent assignment agreement. In February 2010, we amended the agreement to include all intellectual property rights, including patent applications, related to nutraceuticals that increase PPARg 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 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.

**Table of Contents****Preclinical Programs*****MASP-2 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 its abnormal function is associated with a wide range of autoimmune disorders. MASP-2 is generated by the liver and is then released into the circulation. 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 by the deficiency. Therefore, we believe that it may be possible to deliver MASP-2 antibodies systemically and, given our expected dosing requirements, we plan to deliver them subcutaneously.

We have completed a series of in vivo studies using proprietary MASP-2 knock-out mice or MASP-2 antibodies in established models of disease previously linked to activation of the complement system. Our findings suggest that antibody-blockade of MASP-2 may have a preventive or therapeutic effect in the treatment of hemolytic uremic syndrome, or HUS, atypical HUS, or aHUS, paroxysmal nocturnal hemoglobinuria, or PNH, wet age-related macular degeneration, ischemia-reperfusion injury and transplant-related complications. We are continuing to evaluate the role of MASP-2 in these and other complement-mediated disorders. 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. In the second quarter of 2013, we expect to submit a Clinical Trial Application, or CTA, to a European Union member state for OMS721 in preparation for initiating clinical trials this year.

*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.* Pursuant to our exclusive license agreement with Helion, we received a royalty-bearing, worldwide exclusive license in and to all of Helion's intellectual property rights related to MASP-2 antibodies, polypeptides and methods in the field of inhibition of mannan-binding

## **Table of Contents**

lectin-mediated activation of the complement system for the prevention, treatment or diagnosis of any disease or condition. Upon execution of the agreement on April 23, 2010, we made a one-time payment to Helion of \$500,000 and agreed to make development and sales milestone payments to Helion of up to an additional \$6.9 million upon the achievement of certain events, such as the filing of an Investigational New Drug, or IND, application with the FDA; initiation of Phase 2 and 3 clinical trials; receipt of marketing approval; and reaching specified sales milestones. In addition, Helion is entitled to receive a low single-digit percentage royalty of any net sales of a MASP-2 inhibitor product that is 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.

### ***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 movement disorders. Data generated in preclinical studies support both of these potential indications. We have selected a clinical candidate that is undergoing toxicology studies intended to support clinical trials. In mid-2013, we expect to submit an IND application with the FDA and/or a CTA to one or more European Union member states for OMS527 in preparation for initiating clinical trials this year.

*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.

### ***Plasmin Program OMS616***

*Overview.* We are developing antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma or other hyperfibrinolytic conditions. Excessive bleeding during cardiac surgery is known to increase overall morbidity and mortality. In an attempt to control this bleeding, patients undergoing cardiac and

## **Table of Contents**

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 Trasylol® (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 Trasylol® 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. Trasylol® 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 Trasylol®.

Our proprietary agents also inhibit plasmin but, unlike Trasylol®, 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 efficacy, human-protein derivation and improved selectivity of our proprietary agents provide a novel approach to the control of bleeding from surgery and trauma.

*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 Program**

*Overview.* G protein-coupled receptors, or 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



## **Table of Contents**

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, 2013, we had identified and confirmed sets of compounds that interact selectively with, and modulate signaling of, 46 Class A orphan GPCRs linked to a wide range of indications including cancer, metabolic and central nervous system disorders and 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.

*GPCR Platform Funding Agreements with Vulcan Inc. and the Life Sciences Discovery Fund.* On October 21, 2010, we entered into a platform development funding agreement with Vulcan Inc. and its affiliate, which we refer to collectively as Vulcan, pursuant to which we received \$20.0 million for our GPCR program from Vulcan. Also on October 21, 2010, we entered into an agreement with the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or LSDF, under which we received a \$5.0 million grant award from LSDF for expenses that we incurred and equipment we purchased for our GPCR program. Pursuant to the Vulcan and LSDF agreements, we have agreed to pay Vulcan and LSDF tiered percentages of the net proceeds, if any, derived 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. Pursuant to the agreement with Vulcan, at our option, we may pay a portion of Vulcan's share of the one percent of net proceeds to a life sciences initiative, or LSI, to be established pursuant to LSDF agreement. The LSI would be a non-profit organization with a mission to advance life sciences in the State of Washington.

Net proceeds are defined in the Vulcan and LSDF agreements as (1) all consideration received by us in any form relating directly to the GPCR program, such as from license fees, milestone fees, royalties, product sales,

## **Table of Contents**

partnerships and a transfer of the GPCR program to a third party, subject to exceptions specified in such agreements, less (2) all expenses and expenditures in excess of \$25.0 million incurred by us in connection with the GPCR program such as for research and development, related overhead, milestone and royalty payments, legal expenses, cost of goods sold and product sales deductions. 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.

Pursuant to our agreement with Vulcan, we issued to Vulcan 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 exercise price of the warrants may be paid in cash or on a cashless basis in which the number of shares issuable upon exercise of the warrant would be reduced by the number of shares having a fair market value equal to the applicable exercise price. In addition, we agreed to purchase from Patobios Limited, or Patobios, intellectual property assets related to the CRA for consideration consisting of approximately \$10.8 million. We completed the acquisition of these assets on November 22, 2010 by paying to Patobios \$7.6 million in cash and the remaining \$3.2 million in the form of 379,039 shares of our common stock.

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.

Under our agreement with LSDF, after LSDF receives \$25.0 million from us, any remaining amounts that would be payable by us to LSDF pursuant to the agreement will instead 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. We have no other obligations, funding or otherwise, to LSI. 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.

## **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 OMS302, if approved, we intend to use our own internal sales and marketing organization to sell OMS302 in North America and, for markets outside of North America, we intend to work with third parties to perform these services. Because OMS302, if approved, will be used principally by ophthalmologic surgeons in hospital-based and freestanding ambulatory surgery centers, we believe that commercializing OMS302 will only require a limited sales and marketing force. For our other co-lead product OMS103HP, we intend to use a similar approach to market OMS103HP in North America and, for markets outside of North America, we intend to utilize distribution networks or work with third parties to perform these services. Because OMS103HP, if approved, will be used principally by orthopedic surgeons in hospital-based and freestanding ambulatory surgery centers, we believe that commercializing OMS103HP also will only require a limited sales and marketing force.

For the sales and marketing of other products, we generally expect to retain marketing and distribution rights in those for which we believe that it will be possible to access cost-effectively market segments through an

## **Table of Contents**

internal sales and marketing team. If we do not believe that we can cost-effectively access markets for any approved product through an internal sales and marketing force, we expect that we will 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.

We have entered into agreements with Hospira Worldwide, Inc., or Hospira, pursuant to which Hospira has manufactured three registration batches of liquid OMS103HP at its facility in McPherson, Kansas, and agreed to manufacture and supply commercial supplies of liquid OMS103HP, if approved for marketing. Pursuant to our commercial supply agreement with Hospira, Hospira has agreed to supply, and we have agreed to purchase, a minimum quantity of our commercial supply needs of OMS103HP at a price based on the volume of our purchases. If Hospira is unable to supply a minimum quantity of our commercial supply needs, we have the right to reduce our minimum purchase and, in some cases, require Hospira to provide reasonable technology assistance to qualify an alternate supplier or terminate the agreement. We are obligated to provide Hospira with the APIs necessary to manufacture OMS103HP as a liquid solution. Except for our obligation to purchase a minimum quantity of our commercial supply needs of OMS103HP from Hospira, our agreement with Hospira does not limit our ability to use another manufacturer to supply OMS103HP.

The term of the commercial supply agreement continues past the commercial launch of OMS103HP for a five-year period that automatically extends for up to two additional one-year periods unless a party gives notice that it intends to terminate the agreement at least two years prior to the beginning of an extension period. The commercial supply agreement may be terminated at any time prior to the end of its term by a party if the other party (1) materially breaches the agreement and does not cure such breach after notice and an opportunity to cure or (2) goes into liquidation, seeks the benefit of any bankruptcy or insolvency act, or a receiver or trustee is appointed for its property or estate, or it makes an assignment for the benefit of creditors, and such procedures are not terminated within 90 days. We also have the unilateral right to terminate the agreement in whole or in part at any time prior to the end of its term upon the occurrence of specified events such as a regulatory or development set back to OMS103HP that may prevent us from marketing OMS103HP or if we reasonably determine that OMS103HP will not be commercially viable or profitable. In addition, we have the right to terminate the agreement if we are acquired by an independent third party or if we enter into a marketing, promotion or distribution agreement with an independent third party, provided that we may be obligated to continue to purchase liquid OMS103HP from Hospira for a limited amount of time and pay an associated break-up fee. The manufacturing facilities of Hospira have been inspected and approved by the FDA for the commercial manufacture of several third-party drug products.

We utilized multiple suppliers for the APIs used in our clinical supplies of OMS302 and OMS103HP. We have not yet signed commercial agreements with any suppliers for the supply of commercial quantities of these APIs, although we intend to do so prior to the commercial launch of the applicable product. 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 OMS302 and OMS103HP.

## **Table of Contents**

We have not yet entered into a commercial supply agreement for any of our products other than OMS103HP, although we intend to do so prior to the applicable product's commercial launch. Given that there are generally no complicated chemistries or unusual equipment required in 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. If approved, we expect that the primary constraint to market acceptance of our PharmacoSurgery products will be surgeons who continue with their respective current treatment practices and do not adopt the use of these products as well as the level of reimbursement surgeons receive for the administration of our 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 and other diseases that affect cognition. Other pharmaceutical companies, many with significantly greater resources than we, are also developing PDE10 inhibitors for the treatment of schizophrenia and other diseases that affect cognition and these companies may be further along in development. In addition, Soliris® is the only drug approved for the treatment of aHUS and PNH, and our MASP-2 product OMS721 will have to compete with Soliris® if it is approved for either of these indications. Additionally, The Nordic Group is currently authorized to market Trasylol® in Canada for patients undergoing coronary artery bypass graft surgery, and the EMA has recommended to the European Commission that the marketing authorization suspension of Trasylol® be lifted to allow Trasylol® to be marketed again in the European Union. Any product we develop in our Plasmin program for such indication would directly compete with Trasylol® in any countries in which Trasylol® is authorized to be marketed. Also, we are aware that other companies are attempting to de-orphanize orphan GPCRs. If any of these companies is able to de-orphanize an orphan GPCR before we do, we may be unable to establish an exclusive or commercially valuable intellectual property position around that orphan GPCR. 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

## Edgar Filing: OMEROS CORP - Form 10-K

organizations. In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates

## **Table of Contents**

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, 2013, we owned or held worldwide exclusive licenses to a total of 41 issued or allowed patents and 51 pending patent applications in the United States and 167 issued or allowed patents and 163 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 cover 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, 2013, our patent portfolio included 17 U.S. and 67 foreign issued or allowed patents, and 8 U.S. and 19 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 OMS103HP and July 30, 2023 for OMS302, and, if currently pending patent applications are issued, August 3, 2032 for OMS103HP, October 23, 2033 for OMS302 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 OMS302, OMS103HP and OMS201, respectively, as well as covering the specific combinations of agents included in each of these products.

*OMS302 Ophthalmology.* OMS302 is encompassed by our PharmacoSurgery patent portfolio. The relevant patents and patent applications in this portfolio cover 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, 2013, we owned 1 issued U.S. Patent and 2 pending U.S. Patent Applications and 31 issued patents and 9 pending patent applications in foreign markets (Australia, Canada, China, Europe, Hong Kong and Japan) that cover OMS302.

*OMS103HP Arthroscopy.* OMS103HP is encompassed by our PharmacoSurgery patent portfolio. The relevant patents and patent applications in this portfolio cover 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, 2013, we owned 5 issued U.S. Patents, 3 pending U.S. Patent Applications, and 36 issued patents and 4 pending patent applications in foreign markets (Argentina, Australia, Brazil, Canada, China, Europe, Hong Kong, Japan, Mexico, Norway, Russia, Singapore, South Korea and International Patent Cooperation Treaty) that cover OMS103HP.

## Table of Contents

*OMS201 Urology.* OMS201 is encompassed by our PharmacoSurgery patent portfolio. The relevant patents and patent applications in this portfolio cover 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, 2013, we owned 3 issued U.S. Patents, 2 pending U.S. Patent Applications, and an additional 31 issued patents and 9 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, Hong Kong, India, Japan, Mexico, Norway, Russia, Singapore and South Korea) that cover OMS201.

*PDE10 Program OMS824.* As of February 15, 2013, we own 4 issued patent and 2 pending patent applications in the United States, and 22 pending patent applications in foreign markets (Australia, Canada, China, Chile, Europe, India, Indonesia, Israel, Japan, New Zealand and South Africa) that claim proprietary PDE10 inhibitors.

*PPARg Program OMS405.* As of February 15, 2013, we owned 3 pending U.S. Patent Applications and 1 issued patent and 21 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, India, Japan, Mexico, New Zealand, Russia and South Korea) directed to the recently discovered link between PPARg 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, 2013, we exclusively controlled 5 issued patents and 12 pending patent applications in the United States, and 12 issued patents and 53 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Hong Kong, Europe, India, Indonesia, Japan, Mexico, New Zealand, Russia, South Korea and International Patent Cooperation Treaty) related to our MASP-2 program.

*PDE7 Program OMS527.* As of February 15, 2013, we owned 2 pending U.S. Patent Applications, and 2 issued patent and 21 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, India, Japan, Mexico, New Zealand and Russia) directed to the link between PDE7 and movement disorders as well as 2 pending U.S. Patent Applications and 1 international Patent Cooperation Treaty Patent Application directed to the link between PDE7 and addiction and compulsive disorders. Additionally, under a license from Daiichi Sankyo we exclusively control rights to 2 issued U.S. Patents and 1 pending U.S. Patent Application, and 16 issued and 8 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, Hong Kong, Hungary, India, Japan, Korea, Mexico, New Zealand and Russia) that claim 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, 2013, we exclusively controlled 1 issued patent and 1 pending patent application in the United States and 1 issued and 3 pending patent applications in foreign markets (Australia, Canada, Europe and Japan) that are directed to these proprietary agents.

*GPCR Program.* As of February 15, 2013, we owned 5 issued patents and 13 pending patent applications in the United States, and 42 issued patents and 7 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 to research tools that are used in our GPCR program.

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 result

## **Table of Contents**

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 successfully defending 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 United States, 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 United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States 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 our acquisition of nura, inc. in August 2006 for an aggregate purchase price of \$14.4 million.

*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.

*PPARg Program.* We acquired the patent applications and related intellectual property rights for our PPARg program in 2009 from Roberto Ciccocioppo, Ph.D. of the Università di Camerino, Italy, pursuant to a patent assignment agreement. We have agreed to pay Dr. Ciccocioppo royalties and milestone payments related to any products that are covered by the patents we acquired from him. For a more detailed description of this agreement, see Business Clinical Programs PPARg 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 Preclinical Programs MASP-2 Program.

*Plasmin Program.* We hold a worldwide exclusive license to patent rights related to certain antifibrinolytics from The Regents. We have agreed to pay The Regents royalty and development milestone payments under this license.

*GPCR Program.* 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.





## **Table of Contents**

### **Government Regulation**

Government authorities in the United States 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 United States, our products are regulated by the FDA as drugs or biologics under the Federal Food, Drug, and Cosmetic Act and implementing regulations and, in the case of biologics, also under the Public Health Service Act. Before our products may be marketed in the United States, each must be approved by the FDA. Our products are in various stages of testing and none has been approved.

The steps required before a product may be approved by the FDA generally include the following:

preclinical laboratory and animal tests, and formulation studies;

submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin in the United States;

adequate and well-controlled human clinical trials to establish the efficacy and safety of the product for each indication for which approval is sought;

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 an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP; and

FDA review and approval of an NDA or BLA.

*Preclinical Tests.* Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation, and stability, as well as animal studies to assess the potential efficacy and safety of the product. The results of the preclinical tests, together with manufacturing information, analytical data, clinical development plan, and other available information are submitted to the FDA as part of an IND.

*The IND Process.* An IND must become effective before human clinical trials may begin. An IND 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 clinical trials can proceed. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials. Once an IND is in effect there are certain safety and other reporting requirements, and the protocol for each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed.

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

## Edgar Filing: OMEROS CORP - Form 10-K

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.

## **Table of Contents**

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, identify possible adverse side effects and safety risks, and preliminarily evaluate the effectiveness of the product for specific indications.

Phase 3 clinical trials usually further evaluate 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, or the FDA 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, requesting approval to market the product for one or more indications. Before approving an NDA or BLA, the FDA usually will inspect the facility(ies) at which the product is manufactured and will not approve the product unless it finds that cGMP compliance is satisfactory. If the FDA determines the application is not acceptable, the FDA may refuse to accept the application for filing and review, the FDA may outline the deficiencies in the application and often will request additional information. Notwithstanding the submission of any requested additional testing or information, the FDA ultimately may decide that the application does not satisfy the criteria for approval. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims will require submittal of a supplemental application or, in some instances, a new application, for further FDA review and approval. Post-approval use of products in expanded patient populations relative to those that were studied during development can lead to new findings about the safety or efficacy of the products. This information can lead to a product sponsor's requesting approval for and/or the FDA requiring changes in the labeling of the product or even the withdrawal of the product from the market. 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 of applications 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 as well as 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 combination drugs under its Combination Drug Policy (Section 300.50) because they are comprised of two or more active ingredients. The FDA's Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's effectiveness.

Some of our products, such as those from our MASP-2 and Plasmin programs, may be considered biologics because they are derived from living sources as opposed to being chemically synthesized. Biologics and drugs are both subject to regulations under the Federal Food, Drug, and Cosmetic Act, and biologics are also subject to regulation under the Public Health Service Act. In either case, 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 requirements both before and after approval. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotion for our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with

## **Table of Contents**

cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in all areas of regulatory compliance, including production and quality control to comply with cGMP. In addition, discovery of problems such as safety issues may result in changes in labeling or restrictions on a product manufacturer or NDA or BLA holder, including removal of the product from the market.

Outside of the United States, our ability to market our products will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process includes similar requirements and many of the risks associated with the FDA approval process described above. The requirements governing marketing authorization and the conduct of clinical trials may vary from country to country.

## **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 program 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 upon 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 \$31.9 million, \$23.7 million and \$23.5 million in 2012, 2011 and 2010, respectively.

## **Employees**

As of February 28, 2013, we had 71 full-time employees, 55 of whom are in research and development and 16 of whom are in finance, legal, business development and administration, including 4 with M.D.s and 17 with Ph.D.s. None of our employees is represented by a labor union, and we consider our employee relations to be good.

**Table of Contents****Executive Officers and Key Employees**

The following table provides information regarding our executive officers and key employees as of March 18, 2013:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
<i>Executive Officers:</i>		
Gregory A. Demopoulos, M.D.	54	President, Chief Executive Officer and Chairman of the Board of Directors and Interim Chief Financial Officer and Treasurer
Marcia S. Kelbon, J.D., M.S.	53	Vice President, Patent and General Counsel and Secretary
<i>Key Employees:</i>		
Timothy M. Duffy	52	Vice President, Business Development
Kenneth M. Ferguson, Ph.D.	57	Vice President, Development and Chief Development Officer
George A. Gaitanaris, M.D., Ph.D.	56	Vice President, Science and Chief Scientific Officer
Patrick W. Gray, Ph.D.	61	Scientific Fellow
Catherine A. Melfi, Ph.D.	54	Vice President, Regulatory Affairs and Quality Systems
Thomas A. Mitro	55	Vice President, Sales and Marketing
David R. Toll	45	Senior Director of Finance
J. Steven Whitaker, M.D., J.D.	57	Vice President, Clinical Development and Chief Medical Officer
Albert S. Yu, M.D.	56	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 since January 2009. 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.

*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

## **Table of Contents**

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.

*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.

*Thomas A. Mitro* has served as our vice president, sales and marketing, since November 2012. Mr. Mitro previously served from July 2002 until July 2012 as vice president, sales and marketing at ISTA Pharmaceuticals, Inc., which was acquired by Bausch & Lomb Incorporated in June 2012. Before ISTA, Mr. Mitro served for over 20 years in various positions with Allergan, Inc., including as vice president, skin care; vice president, business development; and vice president, e-business. Mr. Mitro received his B.S. from Miami University.

*David R. Toll* has served as our senior director of finance since March 2009. He previously served as our director of finance and controller from January 2006 to March 2009. Mr. Toll also served as our controller and operations manager from November 2000 to January 2006. From 1998 to 2000, he served as the accounting manager at aQuantive, Inc., a publicly traded digital marketing company that was acquired by Microsoft Corporation. From 1992 to 1998, Mr. Toll served in various positions at Ostex International, Inc., a publicly traded biotechnology company and manufacturer of diagnostic kits for osteoporosis that was acquired by Inverness Medical Innovations, Inc. From 1990 to 1992, Mr. Toll served as a staff accountant with Deloitte & Touche LLP. Mr. Toll received his B.A. in business administration from Seattle 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,

## **Table of Contents**

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 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).



## **Table of Contents**

### **ITEM 1A. RISK FACTORS**

*Our business, prospects, financial condition or operating results could be materially adversely affected by any of the risks and uncertainties described below, as well as other risks not currently known to us or by risks that we currently deem immaterial. 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 OMS302 and our success may largely depend on our ability to obtain regulatory approval and to successfully commercialize this product.**

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 and commercialization of our co-lead products OMS302 for use during ILR procedures and OMS103HP for use during arthroscopic partial meniscectomy surgery. We intend to focus a significant portion of our activities and resources on seeking regulatory approval for, and subsequently commercializing, OMS302, and we believe a substantial portion of the value of our company relates to our ability to obtain marketing approval for, and to successfully commercialize, this product.

We are now preparing to submit an NDA and an MAA for OMS302. Before either the FDA or EMA will begin its substantive review of the applicable marketing application, it will conduct a preliminary review to determine whether our submission includes all of the information that such agency believes necessary to evaluate OMS302 for possible marketing approval. The regulatory process is subject to substantial agency discretion and risks, including those described later in these risk factors. If one or both of these agencies refuses to accept our application(s), we may be required to revise our application(s) to include additional information about OMS302, which may require us to conduct additional clinical trials or preclinical studies that may significantly delay our ability to market and generate revenue from the sale of OMS302. Even if our NDA and MAA are accepted for review, either agency may decide not to approve our application, requiring us to obtain additional data regarding OMS302 and to resubmit our marketing application(s), further delaying our ability to market and generate revenue from the sale of OMS302.

Even if we receive regulatory approval for OMS302, our ability to successfully commercialize this product will be subject to numerous uncertainties and risks, including those described later in these risk factors. If there are any negative decisions or delays in the regulatory process or if the anticipated or actual timing and plan for commercializing OMS302, or, ultimately, the market acceptance of OMS302 do not meet our, your, analysts' or others' expectations, the market price of our common stock could decline significantly.

**Our success may also largely depend on the success of OMS103HP, and we cannot be certain that it will receive regulatory approval or be successfully commercialized.**

We are conducting a Phase 3 clinical program evaluating OMS103HP in patients undergoing arthroscopic partial meniscectomy surgery and plan to begin enrolling patients in a second Phase 3 clinical trial in 2013. While OMS103HP demonstrated a drug effect in the first Phase 3 clinical trial by reducing early postoperative pain, we can provide no assurance that in subsequent trials OMS103HP will meet the primary endpoint of early postoperative pain reduction following arthroscopic partial meniscectomy or that more than two additional trials, which we currently expect to conduct, will be required by 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. If the data from any subsequent trials are negative or if we are required to conduct more than two additional clinical trials, we may be unable to seek, or be significantly delayed in seeking, marketing approval of OMS103HP, which could cause the market price of our common stock to decline significantly.

---

**Table of Contents**

**We are subject to extensive government regulation, including the requirement of approval before our products may be marketed.**

Both before and after approval of our products, we, our products, and our suppliers and contract manufacturers are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, 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 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.

Our products cannot be marketed in the United States without FDA approval, and can only be marketed for the indications for which they may be approved. The FDA has not approved any of our products for sale in the United States. All of our products are in development, and will have to be approved by the FDA before they can be marketed in the United States. 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. 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 effectiveness. The FDA has questioned the means by which we intend to demonstrate such contribution and whether available data and information demonstrate contribution for each active ingredient in OMS103HP. 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 those that 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 be able to 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 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, may result in restrictions on any product, manufacturer, or facility, including, among other things, a possible withdrawal of approval of the product.

**Our existing and future products, including our co-lead products OMS302 and OMS103HP, may never achieve market acceptance even if we obtain regulatory approvals.**

Even if we receive regulatory approvals for the commercial sale of one or more of our existing or future products, including OMS302 and OMS103HP, 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

## **Table of Contents**

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 and efficacy;

availability, relative cost and relative efficacy of alternative and competing treatments;

the effectiveness of our marketing and distribution strategy to, among others, hospitals, surgery centers, physicians and/or pharmacists;

prevalence of the condition for which the product is approved or frequency of the related surgical procedure;

acceptance by physicians of each product as a safe and effective treatment;

perceived advantages over alternative treatments;

relative convenience and ease of administration;

the availability of adequate reimbursement by 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 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 become widely accepted by physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable, and if we are unable to increase market penetration of our products, our growth prospects would be significantly harmed.

**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 commonly is commenced 18 months in advance of product launch. Any delay in developing an internal sales force could impact the timing of any product launch. If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any approved products that we develop ourselves. Factors that may inhibit our efforts to commercialize any approved products without collaboration partners include:

our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

## Edgar Filing: OMEROS CORP - Form 10-K

the inability of sales personnel to sell our product(s) to adequate numbers of hospitals, surgery centers, physicians and/or pharmacists to purchase, use or prescribe any approved products;

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.

## **Table of Contents**

### **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 \$38.4 million, \$28.5 million and \$29.3 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, we had an accumulated deficit of approximately \$214.6 million. We do not anticipate generating revenue from the sale of our products until 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.

### **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 OMS302, OMS103HP 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:

submit the NDA and MAA for OMS302 to the FDA and EMA, respectively, and prepare for the product's potential commercialization;

complete the Phase 3 clinical program of OMS103HP for use in arthroscopic partial meniscectomy surgery;

continue the clinical development of OMS824;

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 our PDE7, MASP-2 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 Finance, LLC, or Oxford;

initiate and conduct clinical trials for other products;

make milestone payments to our collaborators; 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 OMS302, if it is approved, or complete all of the clinical trials in our Phase 3 clinical program for OMS103HP, which would prevent us from generating sales revenue for one or both of those products. 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

## Edgar Filing: OMEROS CORP - Form 10-K

increase our development expenses and may require us to raise additional capital to complete their clinical development and commercialization and to decrease spending on our other development programs. Furthermore, we may need to raise additional capital to continue the clinical development of OMS824 and to advance one or more of our preclinical programs into clinical development. If we are unable to raise sufficient capital to commercialize OMS302 or complete the clinical development of OMS103HP 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.

## **Table of Contents**

**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 or comparable 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 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, 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, 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.



---

## **Table of Contents**

**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 agreement with Hospira for the commercial supply of liquid OMS103HP, we have not yet entered into any agreement for the commercial supply of any of our products, including OMS302, and can provide no assurance that we will be able to do so on commercially reasonable terms, if at all. Any significant delays in the manufacture of clinical or commercial supplies of our 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 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 use 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 later 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 current good manufacturing practice requirements strictly enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. We or our contract manufacturers may be unable to comply with current good manufacturing practice requirements or with other FDA, state, local and foreign regulatory requirements. Although we have obligations to review their compliance, we have little control over our 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 for our products will require validation studies, which the FDA must review and approve.

---

## **Table of Contents**

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 sanctions being imposed on us, 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 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 intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of ingredients for our PharmacoSurgery products, we have not yet entered into and we may be unable to secure any 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 ingredients to our contract manufacturers for our clinical trials, potential regulatory approval of our products would be delayed, significantly impacting our ability to develop 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 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.

## **Table of Contents**

**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, 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.

## **Table of Contents**

### **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. 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 Investigational New Drug Application 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 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. We do not currently have agreements in place with manufacturers of biologics to manufacture clinical or commercial quantities of drug product for our MASP-2 or Plasmin programs and cannot be certain that such agreements could be entered into on commercially reasonable terms, if at all. There are only a limited number of manufacturers of biologic drug products. 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, MASP-2, 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.

---

## **Table of Contents**

**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 United States, 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 United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States 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 United States, 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 United States, 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 United States or foreign jurisdictions, which could limit patent protection for our products and materially harm our business.

## **Table of Contents**

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 patents, if issued, or our pending patent applications;

we might not have been the first to file patent applications for these inventions;

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 infringing, 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 United States 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



## **Table of Contents**

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, there is a risk that a court will order us or our contract manufacturers to pay the other party's damages for having violated the other party's patents. We have indemnified 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, these searches 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 United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen 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 proceeding declared by the USPTO to determine priority of invention in the United States. 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 borrowed \$20.0 million pursuant to the terms of a loan and security agreement, as amended, with Oxford, pursuant to which our outstanding principal balance was \$20.0 million as of December 31, 2012. As collateral for this loan, we pledged substantially all of our assets other than intellectual property. Our agreement with Oxford restricts our ability to incur additional indebtedness, pay dividends and engage in significant business transactions such as a change of control of Omeros, so long as we owe any amounts to Oxford under the 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 our agreement, Oxford may have the right to accelerate all of our repayment obligations under the agreement and to take control



---

## **Table of Contents**

of our pledged assets, which include our cash, cash equivalents and short-term investments, potentially requiring us to renegotiate our agreement on terms less favorable to us. Further, if we are liquidated, Oxford's 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 loan and security 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 Oxford declares a default upon the occurrence of any event that it interprets as having a material adverse effect upon us as defined under our agreement, we will be required to repay the loan immediately or to attempt to reverse Oxford's declaration through negotiation or litigation. Any declaration by Oxford 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 facilities 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 Demopoulos, M.D., our president, chief executive officer and chairman of the board of directors and, on an interim basis, our chief financial officer and treasurer. 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.

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 effectively manage 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.

## **Table of Contents**

**We are involved in a lawsuit with one of our former insurance carriers that, if we lose, could materially affect our financial position and cause our stock price to decline.**

Omeros, our chief executive officer and Richard J. Klein, our former chief financial officer and treasurer, entered into a settlement agreement and release effective October 26, 2012, or the Settlement Agreement, under which all of the parties released their respective claims in the lawsuit filed by Mr. Klein. Carolina Casualty Insurance Company, or CCIC, was the carrier for our directors, officers and corporate liability insurance coverage at the time Mr. Klein's employment with us was terminated. On February 21, 2012, CCIC filed a complaint for a declaratory judgment against Omeros, Dr. Demopoulos and Mr. Klein in the U.S. District Court for the Western District of Washington, seeking a declaration that it owes no duty to indemnify or defend us or Dr. Demopoulos against the allegations raised by Mr. Klein. On May 10, 2012, 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.

CCIC has paid, in part, our costs and fees associated with the defense of our lawsuit with Mr. Klein, subject to a reservation of rights. We have paid the remaining portion of the costs and fees of defending the claims raised by Mr. Klein. Additionally, on November 19, 2012 CCIC advanced \$3.95 million to reimburse us for the \$3.94 million payment we made to Mr. Klein under the terms of the Settlement Agreement as well as related employment taxes we paid of approximately \$13,000. CCIC made this payment without waiving any of its rights, including a potential claim seeking recovery of the advanced amount, and without affecting any of our or our chief executive officer's counterclaims, including for failure to defend and bad faith, against CCIC in the pending lawsuit against CCIC. While we are vigorously defending the declaratory judgment action and pursuing our counterclaims, and intend to vigorously defend CCIC's anticipated attempt to recover the settlement funds, we can provide no assurances regarding the outcome of the litigation with CCIC. If we are required to repay to CCIC the settlement funds or any part of our defense costs and fees borne by CCIC, or both, our financial position may be materially negatively affected and our stock price may decline.

**The Settlement Agreement with Mr. Klein does not preclude the U.S. government from seeking recovery from us under the Federal False Claims Act or pursuing other administrative remedies against us.**

During Mr. Klein's employment with us, he used our Whistleblower Policy procedures to report to the chairman of our audit committee that we had submitted grant reimbursement claims in connection with our GPCR program to the National Institutes of Health, or NIH, for work that we had not performed. In accordance with the Whistleblower Policy and its charter, our audit committee, with special outside counsel, commenced an independent investigation of our NIH grant and claims procedures. The investigation concluded that we had not submitted claims to the NIH for work we had not performed. In his subsequent lawsuit against us, Mr. Klein asserted claims on behalf of the United States government under the Federal False Claims Act, or the Qui Tam Claims, which were based on the same NIH grant that was the subject of Mr. Klein's whistleblower report and related NIH grants totaling \$1.3 million. Following an investigation of the Qui Tam Claims, in October 2011 the U.S. government declined to intervene in the lawsuit.

In our subsequent Settlement Agreement with Mr. Klein, he released all of his rights under the Qui Tam Claims. However, because the Qui Tam Claims were made on behalf of the U.S. government, Mr. Klein did not have the authority to settle them on behalf of the U.S. government and such claims accordingly were dismissed without prejudice to the U.S. government. Notwithstanding the Settlement Agreement with Mr. Klein or the U.S. government's earlier decision not to intervene with respect to the Qui Tam Claims, the U.S. government is not precluded from asserting those claims against us under the Federal False Claims Act, or from seeking administrative remedies. We are currently cooperating with an administrative review by the NIH of two grants that were the subject of Mr. Klein's claims. If the U.S. government were to pursue claims under the Federal False Claims Act or any administrative remedies, defending ourselves could require us to spend significant resources and harm our relationship with the NIH, which has continued to award us grants, including for our work in GPCRs, during the course of these proceedings. Additionally, potential remedies under the Federal False Claims

---

## **Table of Contents**

Act include penalties, treble damages and attorneys' fees and costs. If the U.S. government threatens or proceeds with a lawsuit against us or seeks administrative remedies, defending or settling such an action or otherwise settling such possible claims may have a material negative effect on our financial position, harm our reputation and cause our stock price to decline.

### **As a public company we incur increased costs and demands on management as a result of complying with the laws and regulations affecting public companies, which could affect our operating results.**

As a public company we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred, and will continue to incur, costs associated with corporate governance requirements, including 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. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act and the requirements of the related 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.**

If our competitors market products that are less expensive, safer or more effective than our future products developed from our products, that reach the market before our products, or that otherwise negatively affect the market, we may not achieve commercial success. 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 able to develop their products at a faster rate than we are. Pfizer Inc. recently 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

## **Table of Contents**

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. Further, the failure of any future products that we may develop 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.

We expect to compete with other biopharmaceutical and biotechnology companies, and our competitors may:

develop and market products that are less expensive or more effective than any future products that we may develop;

commercialize competing products before we can launch any products that we may develop;

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.

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 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. In addition, physicians may continue with their respective current treatment practices, including the use of current preoperative and postoperative treatments, rather than adopt our PharmacoSurgery products.

**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;

---

**Table of Contents**

finer;

suspension 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.

**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 United States. In order to market our products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may be unable to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The approval procedure varies among countries and can involve additional testing and data review. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these Risk Factors. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other countries, 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 revenue and prospects for profitability could suffer.**

Our future revenue and profit will depend heavily on the availability of adequate reimbursement for the use of our approved products from governmental and other third-party payors, both in the United States 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 is 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

## Edgar Filing: OMEROS CORP - Form 10-K

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

## **Table of Contents**

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 more limited than the purposes for which the product is approved by the FDA or foreign regulatory agencies. 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, sale 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 European Union, 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.

### **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 12-month period ended December 31, 2012, our stock traded as high as \$13.45 per share and as low as \$3.96 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 OMS302;

results from our clinical development programs, including the data from our ongoing clinical development programs evaluating OMS103HP and OMS824;

FDA or international regulatory actions related to any of our other products;

announcements regarding the progress of our preclinical programs and 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;

## Table of Contents

third-party coverage and reimbursement policies;

additions or departures of key personnel;

commencement of, or our involvement in, litigation;

our ability to meet our repayment and other obligations under our loan facility with Oxford, pursuant to which our outstanding principal balance was \$20.0 million as of December 31, 2012;

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 seek 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, except for our committed equity line financing facility described below, we have no commitments for additional capital and cannot be certain that it will be available on acceptable terms, if at all. Continued disruptions in the global equity and credit markets may further limit our ability to access capital. To the extent that we raise additional funds by issuing equity securities, including pursuant to our committed equity line financing facility or our at-the-market equity facility described below, our shareholders may experience significant dilution. Any debt financing, if available, may restrict our operations similar to our debt facility with Oxford. 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

## Edgar Filing: OMEROS CORP - Form 10-K

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

---

## **Table of Contents**

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 shares of our common stock under our at-the-market equity facility or committed equity line financing facility, our existing shareholders will experience immediate dilution and, as a result, our stock price may go down.**

In December 2012, we entered into an at-the-market equity facility, or ATM, with MLV & Co. LLC, or MLV, as sales agent under which we may sell up to \$60.0 million of our common stock by any method deemed to be an at-the-market offering under SEC rules. If we sell shares under the ATM, 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 ATM, the availability of the ATM to us as well as any sales of our common stock under the ATM, should we elect to use it, could encourage short sales by third parties, which could contribute to the further decline of our stock price.

In May 2011, we entered into a committed equity line financing facility under which we are permitted to sell up to \$40.0 million of our common stock to Azimuth Opportunity, Ltd., or Azimuth, over a 24-month period subject to a maximum of 4,427,562 shares of our common stock. If we elect to use the facility, the sale of shares of our common stock to Azimuth will have a dilutive impact on our existing shareholders. Azimuth may resell some or all of the shares we issue to it and such sales could cause the market price of our common stock to decline significantly. To the extent of any such decline, any subsequent advances would require us to issue a greater number of shares of common stock to Azimuth in exchange for each dollar of the advance. Under these circumstances, our existing shareholders would experience greater dilution and the total amount of financing that we will be able to raise pursuant to the facility could be significantly lower than \$40.0 million. In addition, this facility includes terms that limit the amount of committed proceeds we can raise in specified periods, which terms are described in Note 9 to our consolidated financial statements included in this Form 10-K. Because the Azimuth facility will expire on June 1, 2013, taking into account its limitations, we believe that the amount of committed proceeds that we could raise before June 1, 2013 would be significantly less than \$40.0 million. Finally, although Azimuth is precluded from short sales of shares acquired pursuant to advances under the facility, the availability of the facility to us as well as any sales of our common stock under the facility, should we elect to use it, could encourage short sales by third parties, which could contribute to the further decline of our stock price.

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

Approximately 8.2 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

## **Table of Contents**

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 ten percent 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 our loan and security agreement with Oxford, 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 ends in 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 \$508,000 for 2013, \$3.2 million for 2014 and \$3.9 million for 2015 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.

During the first three years of the lease term, 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 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 through 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.

---

**Table of Contents**

**ITEM 3. LEGAL PROCEEDINGS**

Omeros Corporation, Gregory A. Demopoulos, M.D., our chairman, chief executive officer, president and interim chief financial officer, and Richard J. Klein, our former chief financial officer and treasurer, entered into the Settlement Agreement 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 U.S. Securities and Exchange Commission 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 the Qui Tam Claims were dismissed without prejudice to the United States Government, which was not a party to the proceeding.

CCIC was the carrier for our directors, officers and corporate liability insurance policy in effect at the time Mr. Klein's employment with us was terminated. CCIC paid, in part, our defense costs associated with Mr. Klein's lawsuit, subject to a reservation of rights, and we paid the remaining portion of the defense costs. On February 21, 2012, CCIC filed a complaint for a declaratory judgment against Omeros, Dr. Demopoulos and Mr. Klein in the U.S. District Court for the Western District of Washington, seeking a declaration that CCIC owes no duty to indemnify or defend Omeros or Dr. Demopoulos against the allegations raised by Mr. Klein. On May 10, 2012, 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. On November 19, 2012 CCIC paid us \$3.95 million for the \$3.94 million payment we made to Mr. Klein under the terms of the Settlement Agreement as well as related employment taxes we paid of approximately \$13,000. CCIC made this payment without waiving any of its rights, including a potential claim seeking recovery of the \$3.95 million, and without affecting any of our or our chief executive officer's counterclaims against CCIC, including for failure to defend and bad faith. As of March 18, 2013, CCIC has not amended its complaint to seek such recovery, but may choose to do so in the future.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information**

Our common stock has been traded on The NASDAQ Global Market under the symbol OMER since our initial public offering on October 8, 2009. Prior to that time, there was no public market for our common stock.

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

<b>Year Ended December 31, 2012</b>	<b>High</b>	<b>Low</b>
4th Quarter	\$ 11.85	\$ 5.08
3rd Quarter	\$ 10.34	\$ 8.17
2nd Quarter	\$ 13.45	\$ 8.51
1st Quarter	\$ 10.88	\$ 3.96
 <b>Year Ended December 31, 2011</b>	 <b>High</b>	 <b>Low</b>
4th Quarter	\$ 4.15	\$ 3.21
3rd Quarter	\$ 4.37	\$ 3.16
2nd Quarter	\$ 5.50	\$ 3.93
1st Quarter	\$ 8.54	\$ 5.87

**Holders**

As of February 28, 2013, there were approximately 199 holders of record of our common stock.

**Dividends**

We have never declared or paid any cash dividends on our capital stock, and under our loan and security agreement with Oxford 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.

**Table of Contents**

**Stock Performance Graph**

The following graph compares the cumulative total shareholder return for our common stock, the NASDAQ Biotechnology Index and the NASDAQ Composite Index for the period beginning October 8, 2009 (the date of our initial public offering) and ending December 31, 2012. This graph assumes that \$100 was invested on October 8, 2009 in our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. It also assumes that any dividends were reinvested. The data shown in the following graph is not necessarily indicative of future stock price performance.

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



**Table of Contents****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.

	2012	2011	Year Ended December 31,		2009	2008
	(in thousands, except share data)					
<b>Consolidated Statements of Operations and Comprehensive Loss Data:</b>						
Revenue	\$ 6,022	\$ 4,524	\$ 2,105	\$ 1,444	\$ 1,170	
Operating expenses:						
Research and development	31,922	23,718	23,465	16,929	17,850	
Selling, general and administrative	10,985	8,216	8,746	5,273	7,845	
Litigation settlement	3,953					
Litigation recovery	(3,953)					
Total operating expenses	42,907	31,934	32,211	22,202	25,695	
Loss from operations	(36,885)	(27,410)	(30,106)	(20,758)	(24,525)	
Investment income	40	51	167	214	661	
Interest expense	(1,729)	(1,884)	(1,535)	(2,202)	(335)	
Loss on extinguishment of debt			(296)			
Other income (expense)	130	697	2,519	1,657	372	
Net Loss	\$ (38,444)	\$ (28,546)	\$ (29,251)	\$ (21,089)	\$ (23,827)	
Basic and diluted net loss per common share	\$ (1.59)	\$ (1.29)	\$ (1.37)	\$ (2.92)	\$ (8.26)	
Denominator for basic and diluted net loss per common share	24,155,690	22,212,351	21,420,883	7,218,915	2,883,522	

	As of December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except share data)				
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 22,350	\$ 24,570	\$ 41,993	\$ 60,305	\$ 19,982
Working capital (deficit)	15,382	6,963	27,880	49,574	(3,083)
Total assets	26,575	26,982	45,704	62,062	21,681
Total notes payable	20,103	19,446	10,255	12,758	16,674
Accumulated deficit	(214,577)	(176,133)	(147,587)	(118,336)	(97,247)
Total shareholders' (deficit) equity	(6,531)	(5,554)	20,470	43,145	(91,166)

**Table of Contents****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 our audited annual consolidated financial statements and the related notes that appear 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 nura, inc., its wholly owned subsidiary.*

**Overview***Background*

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 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. We currently have five clinical-stage development programs. In addition, we have a deep and diverse pipeline of preclinical programs as well as a platform capable of unlocking new drug targets. For each of our products and programs, we have retained all manufacturing, marketing and distribution rights.

OMS302, one of our co-lead PharmacoSurgery products, successfully completed a Phase 3 clinical program that evaluated the product in patients undergoing ILR surgery. This clinical program consisted of two trials that enrolled both cataract surgery and refractive lens exchange patients. In both Phase 3 clinical trials, OMS302 demonstrated statistically significant superiority over placebo in maintenance of intraoperative mydriasis (pupil dilation) and reduction of early postoperative pain. We are now preparing to submit an NDA to the FDA during the first half of 2013 and an MAA to the EMA in mid-2013 to allow us to market and sell OMS302 in the United States and the European Union, respectively. Assuming approval of at least one of these marketing applications within approximately one year of its submission, we expect to begin marketing OMS302 in 2014.

OMS103HP, our other co-lead PharmacoSurgery product, is being evaluated in a Phase 3 clinical program for its safety and ability to reduce pain following arthroscopic 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 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, OMS103HP achieved statistically significant reduction of postoperative pain. We are preparing to conduct a second Phase 3 clinical trial with reduction of early postoperative pain as the primary endpoint. We expect to begin enrolling patients in this second clinical trial in the first half of 2013.

In addition to OMS302 and OMS103HP, we have a pipeline of other product development programs targeting inflammation, coagulopathies and disorders of the central nervous system. We have the following three clinical-stage programs in our pipeline: (1) our PharmacoSurgery product OMS201 for use during urological surgery, including uroendoscopic procedures, that has completed a Phase 1/Phase 2 clinical trial, (2) our PDE10 program lead compound OMS824 for the treatment of cognitive disorders, including schizophrenia and Huntington's disease, that is currently being evaluated in healthy subjects in a Phase 1 clinical trial and (3) in our

## **Table of Contents**

PPARg program two Phase 2 clinical trials are being conducted by our collaborators to evaluate a PPARg agonist, alone or in combination with other agents, for treatment of addiction to opioids and to nicotine. Our preclinical programs include: (1) our MASP-2 program in which we are developing proprietary MASP-2 antibody therapies to treat disorders associated with complement-activated inflammation (2) our PDE7 program in which we are developing proprietary compounds to treat movement disorders and addiction and compulsive disorders and (3) 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).

In our GPCR program, we are working to complete high-throughput surrogate de-orphanization of orphan GPCRs, or the identification of synthetic molecules that bind and functionally interact with the receptors, and to develop products that act at these new potential drug targets. As of February 28, 2013, we had announced that we have identified and confirmed sets of compounds that interact selectively with, and modulate signaling of, 46 Class A orphan GPCRs. During the fourth quarter of 2010, we entered into an agreement with Vulcan pursuant to which we received \$20.0 million for our GPCR program. Also during the same quarter, we entered into an agreement with the LSDF under which we received a \$5.0 million grant award that was paid to reimburse us for expenses we incurred and equipment purchases related to our GPCR program. In exchange for these payments, we agreed to pay to Vulcan and LSDF a portion of any net proceeds that we receive from the GPCR program. We also issued to the Vulcan affiliate three warrants to purchase our common stock, each with a five-year term and exercisable for up to 133,333 shares, with exercise prices of \$20, \$30 and \$40 per share, respectively.

We recognized net losses of \$38.4 million, \$28.5 million, and \$29.3 million for the years ended December 31, 2012, 2011 and 2010, respectively. These losses have resulted 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 products. Compared to 2012, we expect our net losses to increase as we continue to advance our clinical trials, expand our research and development efforts, add personnel for our anticipated growth and prepare for the commercial launch of OMS302, if it is approved. As of December 31, 2012, our accumulated deficit was \$214.6 million and total shareholders' deficit was \$6.5 million.

### *Revenue*

Our revenue to date has consisted of grant funding from third parties and revenue recognized in connection with funding from Vulcan and LSDF. Other than grant funding, we do not expect to receive any revenue from our products until we receive regulatory approval and commercialize the products or until we potentially enter into collaborative agreements with third parties for the development and commercialization of our products. As discussed below, we do not expect any of our current products to be commercially available before 2014, if at all. We continue to pursue government and private grant funding as well as collaboration funding for our products and research programs.

### *Research and Development Expenses*

The majority of our operating expenses to date have been for research and development activities. Research and development expenses consist of costs associated with research activities as well as costs associated with our product development efforts, which include clinical trial and third-party manufacturing services. Internal research and development costs are recognized as incurred. Third-party research and development costs are expensed at the earlier of when the contracted work has been performed or when upfront and milestone payments are made. Research and development expenses include:

employee and consultant-related expenses, which include salaries and benefits;

external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, CROs, clinical trial sites, and collaborators or licensors;

**Table of Contents**

facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and depreciation of leasehold improvements and equipment; and

third-party supplier expenses including laboratory and other supplies.

Our research and development expenses can be divided into clinical research and development and preclinical research and development activities. The following table illustrates our expenses associated with these activities:

	Years Ended December 31,		
	2012	2011	2010
	(in thousands)		
<b>Direct external expenses</b>			
Clinical research and development			
OMS302	\$ 8,622	\$ 4,663	\$ 2,837
OMS103HP	2,773	3,558	5,581
PDE10	990		
Other clinical programs	52	72	248
<b>Total clinical research and development</b>	<b>12,437</b>	<b>8,293</b>	<b>8,666</b>
Preclinical research and development	6,019	5,005	4,054
<b>Total direct external expenses</b>			
Internal, overhead and other expenses	11,275	9,601	9,774
Stock-based compensation expense	2,191	819	971
<b>Total research and development expenses</b>	<b>\$ 31,922</b>	<b>\$ 23,718</b>	<b>\$ 23,465</b>

Direct external clinical research and development expenses consist primarily of external research and development and regulatory expenses incurred pursuant to agreements with third-party manufacturing organizations, CROs, clinical trial sites, collaborators, licensors and consultants. Direct external preclinical research and development expenses consist primarily of our preclinical research activities, laboratory supplies and consulting. Internal, overhead and other expenses consist of personnel costs and other overhead costs such as rent, utilities and depreciation. Our internal resources, employees and infrastructure are not directly tied to any individual research project and are typically deployed across multiple clinical and preclinical projects that we are advancing in parallel.

At this time, due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage 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 for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. While we are currently focused on advancing each of 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 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. We do not expect any of our current products to be commercially available before 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 projects.

## **Table of Contents**

### **Results of Operations**

#### *Comparison of Years Ended December 31, 2012 and December 31, 2011*

**Revenue.** 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 that we recognized from both the Vulcan agreement and NIH grants for preclinical research. This increase was partially offset by a decrease in revenue recognized under our agreements with LSDF and SMRI given that all remaining revenue under those agreements was recognized during the first quarter of 2012 and second quarter of 2011, respectively.

**Research and Development Expenses.** Research and development expenses were \$31.9 million and \$23.7 million for the years ended December 31, 2012 and 2011, respectively. The increase in 2012 was primarily due to higher expenses related to our OMS302 Phase 3 clinical program, advancing our PDE10 and MASP-2 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 OMS103HP program and in several of our preclinical programs, including our PDE7 and Plasmin programs.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses were \$11.0 million and \$8.2 million for the years ended December 31, 2012 and 2011, respectively. The increase was primarily due to higher legal costs, marketing expenses tied to the planned 2014 commercial launch of OMS302 and employee compensation, including non-cash stock-based compensation.

**Interest Expense.** Interest expense was \$1.7 million and \$1.9 million for the years ended December 31, 2012 and 2011, respectively. Interest expense decreased in 2012 due to a lower average notes payable balance.

**Other Income, net.** Other income, net was \$130,000 and \$697,000 for the years ended December 31, 2012 and 2011, respectively. On March 28, 2012, we extended the expiration date of warrants to purchase up to an aggregate of 197,478 shares of our common stock and recognized other expense of \$511,000 in connection with the warrant modification. The remaining decrease relates primarily to lower rental income received under our subleases.

#### *Comparison of Years Ended December 31, 2011 and December 31, 2010*

**Revenue.** Revenue was \$4.5 million and \$2.1 million for the years ended December 31, 2011 and 2010, respectively. The increase was primarily due to higher revenue that we recognized from our agreements with Vulcan and LSDF, partially offset by a decrease in revenue recognized in connection with the completion of preclinical research funded by NIH grants.

**Research and Development Expenses.** Research and development expenses were \$23.7 million and \$23.5 million for the years ended December 31, 2011 and 2010, respectively. The increase in 2011 was primarily due to higher expenses associated with our OMS302 Phase 3 clinical program and higher GPCR program expenses. These increases were partially offset by lower expenses associated with the completion of our Phase 3 program evaluating OMS103HP in arthroscopic anterior cruciate ligament reconstruction and lower one-time licensing fees.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses were \$8.2 million and \$8.7 million for the years ended December 31, 2011 and 2010, respectively. The decrease was primarily due to lower costs associated with the replacement of our initial 2010 committed equity line financing facility with Azimuth and lower employee expenses.

**Investment Income.** Investment income was \$51,000 and \$167,000 for the years ended December 31, 2011 and 2010, respectively. The decrease is due primarily to lower average investment balances in 2011.

## **Table of Contents**

*Interest Expense.* Interest expense was \$1.9 million and \$1.5 million for the years ended December 31, 2011 and 2010, respectively. Interest expense increased in 2011 due to a higher average notes payable balance.

*Loss on Extinguishment of Debt.* The loss on extinguishment of debt was \$296,000 for the year ended December 31, 2010 and relates entirely to losses incurred as a result of the refinancing of our debt with Oxford.

*Other Income, net.* Other income, net was \$697,000 and \$2.5 million for the years ended December 31, 2011 and 2010, respectively. The increase in 2011 was primarily due to income received from the U.S. Qualifying Therapeutic Discovery Project Program.

## **Liquidity and Capital Resources**

We have financed our operations primarily through (1) private and public placements of equity securities for proceeds totaling \$171.5 million, \$32.3 million of which we received, net of expenses, from the sale of 3,365,854 shares of common stock at a price of \$10.25 per share in a public offering completed on July 2, 2012; (2) two debt facilities with loan proceeds totaling \$44.2 million, with \$9.0 million of proceeds from the second facility used to pay off the remaining balance of the first facility; and (3) our GPCR program funding agreement with Vulcan pursuant to which we received \$20.0 million. Additionally, we received a \$3.0 million cash lease incentive payment in the first quarter of 2012 related to our new office and laboratory lease with BMR-201 Elliott Avenue LLC, or BMR, for The Omeros Building. As of December 31, 2012, we had \$22.4 million in cash, cash equivalents and short-term investments. Our cash, cash equivalents and short-term investment balances are held principally in interest-bearing instruments, including money-market accounts. Cash in excess of immediate requirements is invested in accordance with established guidelines to preserve principal and maintain liquidity. We believe that our existing cash, cash equivalents and short-term investments and capital that we may be able to raise under our agreements with MLV or Azimuth will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months.

### *Comparison of Years Ended December 31, 2012 and December 31, 2011*

*Operating Activities.* Net cash used in operating activities was \$34.6 million and \$25.7 million for the years ended December 31, 2012 and 2011, respectively. Expenditures related to operating activities in these periods were primarily related to research and development expenses and selling, general and administrative expenses in support of our operations. The increase was primarily due to higher costs to support our Phase 3 OMS302 clinical program, our MASP-2, GPCR and PDE10 programs as well as higher employee costs. These increases were partially offset by the \$3.0 million cash lease incentive payment that we received from BMR during the first quarter of 2012.

*Investing Activities.* Net cash used in investing activities was \$907,000 for the year ended December 31, 2012 compared to cash provided by investing activities of \$16.9 million for the year ended December 31, 2011. Investing activities, other than 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 equivalent 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.

*Financing Activities.* Net cash provided by financing activities was \$33.0 million and \$9.5 million for the years ended December 31, 2012 and 2011, respectively. Net cash provided from financing activities in 2012 was due primarily to \$32.3 million in net proceeds from the sale of common stock in our public offering in July 2012 and \$6.4 million in net proceeds from our debt refinancing in December 2012. Net cash provided by financing activities in 2011 was primarily the result of our borrowing \$10.0 million under the second tranche of our loan from Oxford in March 2011. In both periods, net cash provided by financing activities was partially offset by principal payments on our notes payable.

## **Table of Contents**

### *Comparison of Years Ended December 31, 2011 and December 31, 2010*

*Operating Activities.* Net cash used in operating activities was \$25.7 million and \$14.5 million for the years ended December 31, 2011 and 2010, respectively. Expenditures related to operating activities in these periods were primarily related to research and development expenses and selling, general and administrative expenses in support of our operations. Cash used to fund operating activities was lower for the year ended December 31, 2010, primarily due to the cash received from our Vulcan agreement, which was recorded as deferred revenue in 2010 and is being amortized to revenue as research is performed.

*Investing Activities.* Net cash provided by investing activities was \$16.9 million and \$19.9 million for the years ended December 31, 2011 and 2010, respectively. Investing activities, other than purchases, sales and maturities of short-term investments, consist primarily of purchases of property and equipment. In 2010, investing activities also included our acquisition of intellectual property assets from Patobios and our subsequent reimbursement of the purchase price by Vulcan. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and receipts from the sale and maturity of short-term investments, thus causing a shift between our cash and cash equivalent 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.

*Financing Activities.* Net cash provided by financing activities was \$9.5 million for the year ended December 31, 2011, primarily as a result of our borrowing of the second \$10.0 million tranche from Oxford in March 2011, partially offset by principal payments to Oxford, which began in November 2011. Net cash used in financing activities was \$3.0 million for the year ended December 31, 2010 and was primarily due to the payoff of our loan from BlueCrest Venture Finance Master Fund Limited, partially offset by proceeds received from the first \$10.0 million tranche of our Oxford loan.

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

In December 2012, we entered into an at-the-market issuance sales agreement, or the Sales Agreement, with MLV pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to \$60.0 million directly on The NASDAQ Global Market or sales made to or through 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 shares under the Sales Agreement, or, if we do, 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 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.

### *Azimuth Committed Equity Line Financing Facility*

In May 2011, we entered into a committed equity line financing facility with Azimuth pursuant to which we are permitted to sell up to \$40.0 million of our shares of common stock over a 24-month term. This facility replaced a prior committed equity line financing facility, which we entered into with Azimuth on July 28, 2010 but had not accessed. Under the 2011 agreement with Azimuth, we may, from time to time over the 24-month term and in our sole discretion, present Azimuth with draw down notices requiring Azimuth to purchase a specified dollar amount of shares of our common stock, based on the volume-weighted average price per share on each of 10 consecutive trading days, or the draw down period, with the total dollar amount of each draw down subject to

## **Table of Contents**

certain agreed-upon limitations based on the market price of our common stock at the time of the draw down. The purchase price for these shares equals the daily volume-weighted average price of our common stock on each date during the draw down period on which shares are purchased, less a discount ranging from 3.00% to 6.00%, based on a minimum price that we specify. We are allowed to present Azimuth with up to 24 draw down notices during the 24-month term, with only one such draw down notice allowed per draw down period and a minimum of five trading days required between each draw down period. We may not issue more than 4,427,562 shares in connection with the committed equity line financing facility, although this limitation does not apply if the average purchase price of all shares issued to Azimuth, taking into account all discounts, equals or exceeds \$5.02 per share, which amount is subject to adjustment in certain circumstances specified in the facility. We have not drawn down funds under this facility to date and it will expire on June 1, 2013 unless we and Azimuth mutually agree to extend it. Because the facility will expire on June 1, 2013, taking into account its limitations described above, we believe that the amount of committed proceeds that we could raise before June 1, 2013 would be significantly less than \$40.0 million. We are unable to estimate the actual amount as it depends on the price of our stock at the time we use the facility.

In connection with this facility, we entered into a placement agent agreement with Reedland Capital Partners, an Institutional Division of Financial West Group, member FINRA/SIPC, or FWG/Reedland. We have agreed to pay FWG/Reedland, upon each sale of our common stock to Azimuth under the facility, a fee equal to 0.5% of the aggregate dollar amount of common stock purchased by Azimuth.

### *Stanley Medical Research Institute Funding Agreement*

In December 2006, we entered into a funding agreement with SMRI to develop a proprietary product that inhibits PDE10 for the treatment of schizophrenia. Under the agreement, we may receive grant and equity funding upon achievement of product development milestones through Phase 1 clinical trials totaling \$9.0 million, subject to our mutual agreement with SMRI. As of December 31, 2012, we had received \$5.7 million from SMRI, \$2.5 million of which was recorded as revenue and \$3.2 million of which was recorded as equity funding.

### *Oxford Loan and Security Agreement*

In October 2010, we entered into a loan and security agreement, or the Loan Agreement, with Oxford pursuant to which Oxford agreed to lend us up to \$20.0 million in two tranches of \$10.0 million each. We borrowed the first tranche in October 2010, or Tranche 1, and the second tranche in March 2011, or Tranche 2. On December 28, 2012, we entered into an amendment to the Loan Agreement, or the Amendment, pursuant to which we borrowed an additional \$7.2 million, or Tranche 3, and amended the repayment terms of the existing outstanding indebtedness under Tranche 1 and Tranche 2. The Amendment provides for interest-only payments on Tranche 1, Tranche 2 and Tranche 3 through December 31, 2013. Beginning on January 1, 2014, 36 payments of principal and interest are payable monthly, in arrears. All unpaid principal and accrued and unpaid interest are due and payable on the maturity date, December 1, 2016. As a result of Tranche 3, our total outstanding principal to Oxford was \$20.0 million as of December 31, 2012. Interest on the \$20.0 million accrues at an annual fixed rate of 9.25%. We are using the proceeds from Tranche 3 for working capital and general business purposes.

Prior to the Amendment, upon borrowing Tranche 1 and Tranche 2, we recorded a \$900,000 discount on the notes related to a final payment fee and we capitalized in other assets \$227,000 in debt issuance costs. Both the discount and the debt issuance costs were amortized to interest expense using the effective-interest method over the repayment term of the initial loan amount. In connection with the Amendment, we paid \$588,000 for the prorated portion of the \$900,000 final payment due under Tranche 1 and Tranche 2 with no further obligation for the remaining \$312,000. We accounted for the Amendment as a debt modification rather than an extinguishment of debt. Accordingly, the remaining unamortized costs associated with the original debt will be amortized to interest expense using the effective-interest method over the amended repayment term.



## **Table of Contents**

In connection with the Amendment, we agreed to pay Oxford a final payment fee equal to 7.0% of the borrowed \$20.0 million, or \$1.4 million, which we recorded as a discount on the outstanding debt. The final payment fee will be due upon the last payment date of the amounts we borrowed, whether upon maturity on December 1, 2016, or on the date of any prepayment of such amounts or in the event of acceleration upon a default. We also capitalized in other assets \$168,000 in debt issuance costs that we incurred. Both of these amounts are being amortized to interest expense using the effective-interest method over the amended repayment term. As of December 31, 2012, unamortized discount and debt issuance costs associated with the modified debt was \$1.4 million and \$168,000, respectively.

We may prepay the outstanding principal balance in its entirety, plus accrued and unpaid interest, at any time upon delivery of prior notice to Oxford and the payment of a prepayment fee equal to 1.0% of the then-outstanding principal amount, which prepayment fee would be waived if we refinance the indebtedness with Oxford. As security for its obligations under the Loan Agreement, we granted Oxford a security interest in substantially all of our assets, excluding intellectual property. The Loan Agreement contains customary affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, 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, or repurchase stock, in each case subject to customary exceptions for a loan agreement of this size and type. The Loan Agreement contains no cash covenant.

The Loan Agreement includes customary events of default that include, among other things, 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 our indebtedness to Oxford. Under certain circumstances, a default interest rate will apply on all obligations during the existence of an event of default under the Loan Agreement at a per annum rate equal to 5.0% above the otherwise applicable interest rate.

MAE is defined in the Loan Agreement as a material adverse effect upon (i) the 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 Loan Agreement, (ii) the validity, perfection, value or priority of Oxford's security interest in the collateral, (iii) the enforceability of any material provision of the Loan Agreement or related agreements or (iv) the ability of Oxford to enforce its rights and remedies under the Loan Agreement or related agreements. We considered the MAE definition and believe that the MAE clause has not been triggered as of December 31, 2012.

### *Carolina Casualty Insurance Company Litigation*

Under the terms of the Settlement Agreement discussed in Item 3 Legal Proceedings to this Annual Report on Form 10-K, we made a one-time payment of \$3.94 million to Mr. Klein to release all of his claims, which included a claim for payment of his attorneys' fees since 2009 incurred in connection with the lawsuit. As of December 31, 2012, we recorded \$3.95 million as litigation settlement on the accompanying statements of operations and comprehensive loss. As also described in Item 3 Legal Proceedings to this Annual Report on Form 10-K, we are currently engaged in litigation with CCIC, which was the carrier for our directors, officers and corporate liability insurance policy in effect at the time Mr. Klein's employment with us was terminated.

On November 19, 2012 CCIC reimbursed us \$3.95 million for the payment we made to Mr. Klein as well as related employment taxes we paid. During the quarter ended December 31, 2012, we recorded \$3.95 million as a recovery on settlement on the accompanying statements of operations and comprehensive loss. CCIC made this payment without waiving any of its rights, including a potential claim seeking recovery of the \$3.95 million, and without affecting any of our or our chief executive officer's counterclaims against it, including for failure to

## **Table of Contents**

defend and bad faith. As of March 18, 2013, CCIC has not amended its complaint to seek such recovery, but may choose to do so in the future. The ultimate financial impact of this action is not yet determinable. If we are required to repay to CCIC the settlement funds or any part of our defense costs and fees borne by CCIC, or both, our financial position may be materially negatively affected.

### *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;

costs related to manufacturing services;

whether the hiring of a number of new employees to support our continued growth during this period will occur at salary levels consistent with our estimates;

the terms and timing of payments of any collaborative or licensing agreements that we have or may establish;

the cost, timing and outcomes of the regulatory processes for our products;

the costs of commercialization activities, including product manufacturing, marketing, sales and distribution;

the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

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;

whether we receive grant funding for our programs;

the extent to which we raise capital by selling our stock through our at-the-market equity facility with MLV, under which MLV is required to use its commercially reasonable efforts to sell our stock in accordance with our instructions;

the extent to which we raise capital from Azimuth under our committed equity line financing facility, which will expire on June 1, 2013 unless we and Azimuth mutually agree to extend it;

the extent to which we otherwise access the capital markets; and

## Edgar Filing: OMEROS CORP - Form 10-K

the amount of revenue we generate from the sale of our products, which revenue we do not expect until at least 2014.

We expect our continuing operating losses to result in an increasing total amount of cash used in operations over the next several years. To meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we do not raise additional capital through equity or debt financings and/or one or more corporate partnerships, we may be required to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts. Except for our committed equity line financing facility with Azimuth which expires on June 1, 2013, we currently do not have any commitments for future external equity or debt funding. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all, and any future equity funding will dilute the ownership of our equity investors.

**Table of Contents****Contractual Obligations and Commitments**

The following table presents a summary of our contractual obligations and commitments as of December 31, 2012.

	Payments Due Within				
	1 Year	2-3 Years	4-5 Years	More than	Total
			(in thousands)	5 Years	
Operating leases	\$ 510	\$ 7,129	\$ 8,145	\$ 45,928	\$ 61,712
License maintenance fees	7	14	30	100	151
Capital leases (principal and interest)	57	94	12		163
Notes payable (principal and interest)	1,696	15,320	7,660		24,676
<b>Total</b>	<b>\$ 2,270</b>	<b>\$ 22,557</b>	<b>\$ 15,847</b>	<b>\$ 46,028</b>	<b>\$ 86,702</b>

We currently lease our office and laboratory space in The Omeros Building under the Lease 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. We have received net lease incentives of \$4.6 million, which were recorded as deferred rent on our accompanying consolidated balance sheet. Please see Note 8 to our consolidated financial statements in this Annual Report on Form 10-K for additional discussion of the Lease. The contractual commitment amounts in the table above are associated with agreements that are enforceable and legally binding.

We may also be required to make royalty and milestone payments that are not listed in the table above because we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur. Please 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.

**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 United States. 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.



**Table of Contents***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.

Our revenue relates to grant funding from third parties and revenue recognized in connection with funding from Vulcan and LSDF. We recognize such funds as revenue 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 expenses are comprised primarily of employee and consultant-related expenses, which include salaries and benefits; external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, CROs and clinical trial sites; facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and depreciation of leasehold improvements and equipment; third-party supplier expenses, including laboratory and other supplies; and payments to collaborators and licensors. 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. Internal and third-party research and development expenses are expensed as incurred.

*Stock-Based Compensation*

Stock-based compensation cost is estimated at the grant date based on the award's fair value and is recognized on the straight-line method as expense over the requisite service period, which is generally the vesting period. Compensation cost for all stock-based awards is measured at fair value as of the grant date. The fair value of our stock options is calculated using the Black-Scholes option valuation model. The Black-Scholes model requires the input of various subjective assumptions, including stock price volatility 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 in the future from that recorded in the current period.

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**

In June 2011, the Financial Accounting Standards Board issued an Accounting Standards Update, or ASU, related to the presentation of comprehensive income that requires companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. It eliminated the option to present components of other comprehensive income as part of the statement of changes in shareholders' equity. The standard does not change the items that must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. This standard, which

## **Table of Contents**

must be applied retroactively, was effective for interim and annual periods beginning after December 15, 2011. We adopted the standards on January 1, 2012 and now present a combined statement of operations and comprehensive loss in our accompanying financial statements.

### **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 interest rate risk that may affect our investment securities. 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 a variety of securities of high credit quality. As of December 31, 2012, we had cash, cash equivalents and short-term investments of \$22.4 million. We have invested these funds in highly liquid, investment-grade securities in accordance with our investment policy. The 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 interest 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 officer, 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, 2012. 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, 2012, 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.

## **Table of Contents**

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 officer, conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2012. 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. 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, 2012.

Ernst & Young LLP has independently assessed the effectiveness of our internal control over financial reporting as of December 31, 2012 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 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



---

**Table of Contents**

**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, 2012 based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (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, 2012, 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 at December 31, 2012 and 2011, 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, 2012 and our report dated March 18, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington

March 18, 2013

**Table of Contents**

**ITEM 9B. OTHER INFORMATION**

None.

**Table of Contents****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 2013 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 2013 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 2013 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, 2012:

	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)	3,610,292	\$ 7.11	884,578
Second Amended and Restated 1998 Stock Option Plan	1,777,772	1.27	
nura, inc. 2003 Stock Option Plan	2,518	10.63	
<b>Total</b>	<b>5,390,582</b>	<b>\$ 5.18</b>	<b>884,578</b>

- (1) Upon adoption of the 2008 Equity Incentive Plan, we reserved a total of 892,857 shares of our common stock for issuance thereunder plus any shares returned to the Second Amended and Restated 1998 Stock Option Plan as a result of termination of options or repurchase of shares issued pursuant to such plan, with the maximum number of shares returned equal to 3,084,848 shares. In addition, our 2008 Equity Incentive 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 least of: (1) five percent of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year; (2) 1,785,714 shares; and (3) such other amount as our board of directors may determine. On January 1, 2013, an additional 1,294,874 shares became available for future issuance under our 2008 Equity Incentive 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 2013 Annual Meeting of Shareholders and is incorporated herein by reference.

**Table of Contents**

**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 2013 Annual Meeting of Shareholders and is incorporated herein by reference.

**Table of Contents**

**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.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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**

By: /s/ Gregory A. Demopulos, M.D.  
 Gregory A. Demopulos, M.D.  
 President, Chief Executive Officer

and Chairman of the Board of Directors

Date: March 18, 2013

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ GREGORY A. DEMOPULOS, M.D.  Gregory A. Demopulos, M.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer, Principal Accounting Officer and Principal Financial Officer)	March 18, 2013
/s/ RAY ASPIRI  Ray Aspiri	Director	March 18, 2013
/s/ THOMAS J. CABLE  Thomas J. Cable	Director	March 18, 2013
/s/ PETER A. DEMOPULOS, M.D.  Peter A. Demopulos, M.D.	Director	March 18, 2013
/s/ ARNOLD C. HANISH  Arnold C. Hanish	Director	March 18, 2013
/s/ LEROY E. HOOD, M.D., PH.D.  Leroy E. Hood, M.D., Ph.D.	Director	March 18, 2013

**Table of Contents**

**OMEROS CORPORATION**

**INDEX TO FINANCIAL STATEMENTS**

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

F-1



**Table of Contents**

**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, 2012 and 2011, 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, 2012. 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, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Omeros Corporation's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 18, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington

March 18, 2013

**Table of Contents**

**OMEROS CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**

(In thousands except share and per share data)

	December 31, 2012	2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,520	\$ 4,005
Short-term investments	20,830	20,565
Grant and other receivables	1,934	876
Prepaid expenses and other current assets	416	502
 Total current assets	 24,700	 25,948
Property and equipment, net	1,037	739
Restricted cash	679	193
Other assets	159	102
 Total assets	 26,575	 \$ 26,982
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,632	\$ 2,002
Accrued expenses	5,716	5,340
Deferred revenue	970	5,748
Current portion of notes payable, net of discount		5,895
 Total current liabilities	 9,318	 18,985
Notes payable, net of current portion and discount	20,103	13,551
Deferred rent, net of current portion	3,685	
Commitments and contingencies		
 Shareholders' equity:		
Preferred stock, par value \$0.01 per share:		
Authorized shares 20,000,000 at December 31, 2012 and 2011;		
Issued and outstanding shares none		
Common stock, par value \$0.01 per share:		
Authorized shares 150,000,000 at December 31, 2012 and 2011;		
Issued and outstanding shares 25,897,483 and 22,430,234 at December 31, 2012 and 2011, respectively	259	224
Additional paid-in capital	207,787	170,355
Accumulated deficit	(214,577)	(176,133)
 Total shareholders' deficit	 (6,531)	 (5,554)
 Total liabilities and shareholders' equity	 \$ 26,575	 \$ 26,982

See notes to consolidated financial statements

**Table of Contents****OMEROS CORPORATION****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(In thousands, except share and per share data)**

	<b>Year Ended December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Revenue	\$ 6,022	\$ 4,524	\$ 2,105
Operating expenses:			
Research and development	31,922	23,718	23,465
Selling, general and administrative	10,985	8,216	8,746
Litigation settlement	3,953		
Litigation recovery	(3,953)		
Total operating expenses	42,907	31,934	32,211
Loss from operations	(36,885)	(27,410)	(30,106)
Investment income	40	51	167
Interest expense	(1,729)	(1,884)	(1,535)
Loss on extinguishment of debt			(296)
Other income, net	130	697	2,519
Net loss	\$ (38,444)	\$ (28,546)	\$ (29,251)
Realized loss on sale of available-for-sale securities			(41)
Comprehensive loss	\$ (38,444)	\$ (28,546)	\$ (29,292)
Basic and diluted net loss per share	\$ (1.59)	\$ (1.29)	\$ (1.37)
Weighted-average shares used to compute basic and diluted net loss per share	24,155,690	22,212,351	21,420,883

See notes to consolidated financial statements

**Table of Contents****OMEROS CORPORATION****CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY (DEFICIT)**

(In thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)		Accumulated Deficit	Total Shareholders Deficit
	Shares	Amount					
Balance at December 31, 2009	21,285,577	\$ 213	\$ 161,227	\$ 41		\$ (118,336)	\$ 43,145
Issuance of common stock warrants in connection with Vulcan funding agreement			994				994
Issuance of common stock to Patobios at \$8.30 per share in connection with GPCR technology purchase	379,039	4	3,142				3,146
Issuance of common stock upon exercise of stock options for cash of \$0.52 to \$6.05 per share	256,220	2	297				299
Stock-based compensation			2,178				2,178
Realized loss on sale of available-for-sale securities				(41)			(41)
Net loss						(29,251)	(29,251)
Balance at December 31, 2010	21,920,836	219	167,838			(147,587)	20,470
Issuance of common stock upon exercise of stock options for cash of \$0.52 to \$2.45 per share	509,398	5	590				595
Stock-based compensation			1,927				1,927
Net loss						(28,546)	(28,546)
Balance at December 31, 2011	22,430,234	224	\$ 170,355			(176,133)	(5,554)
Issuance of common stock for \$10.25 per share in public offering, net of offering costs of \$2.2 million	3,365,854	34	32,272				32,306
Issuance of common stock upon exercise of stock options for cash of \$0.76 to \$7.56 per share	101,395	1	368				369
Stock-based compensation			4,281				4,281
Warrant modification			511				511
Net loss						(38,444)	(38,444)
Balance at December 31, 2012				\$			
	25,897,483	\$ 259	\$ 207,787			\$ (214,577)	\$ (6,531)

See notes to consolidated financial statements

**Table of Contents**

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

(In thousands)

	Year Ended December 31 ,		
	2012	2011	2010
<b>Operating activities</b>			
Net loss	\$ (38,444)	\$ (28,546)	\$ (29,251)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	320	435	472
Stock-based compensation expense	4,281	1,927	2,178
Non-cash interest expense	354	352	174
Loss on extinguishment of debt			296
Warrant modification expense and other	511		33
Changes in operating assets and liabilities:			
Grant and other receivables	(1,059)	2,254	(1,231)
Prepaid expenses and other current and noncurrent assets	(438)	(201)	(87)
Accounts payable and accrued expenses	957	339	1,462
Deferred revenue	(4,718)	(2,228)	11,452
Deferred rent, net of current portion	3,685		
Net cash used in operating activities	(34,551)	(25,668)	(14,502)
<b>Investing activities</b>			
Purchases of property and equipment	(642)	(1,241)	(807)
Purchase of Patobios intellectual property assets			(7,631)
Reimbursement of Patobios intellectual property assets			7,631
Purchases of investments	(49,547)	(9,000)	(57,765)
Proceeds from the sale of investments	49,282	27,150	78,173
Proceeds from the maturities of investments			323
Net cash (used in) provided by investing activities	(907)	16,909	19,924
<b>Financing activities</b>			
Proceeds from issuance of common stock upon public offering	32,306		
Net proceeds from borrowings under note payable	6,492	9,942	9,742
Payments on notes payable	(6,194)	(1,051)	(13,005)
Proceeds from issuance of common stock upon exercise of stock options	369	595	299
Net cash provided by (used in) financing activities	32,973	9,486	(2,964)
Net (decrease) increase in cash and cash equivalents	(2,485)	727	2,458
Cash and cash equivalents at beginning of period	4,005	3,278	820
Cash and cash equivalents at end of period	\$ 1,520	\$ 4,005	\$ 3,278
<b>Supplemental cash flow information</b>			
Cash paid for interest	\$ 1,502	\$ 1,461	\$ 1,362
Issuance of common stock to Patobios in connection with purchase of intellectual property assets	\$	\$	\$ 3,146

## Edgar Filing: OMEROS CORP - Form 10-K

Reduction of equipment cost basis due to assets purchased with grant funding	\$	59	\$	1,689	\$
Issuance of warrants in connection with the Vulcan funding agreement	\$		\$		\$ 994
Property acquired under capital lease	\$	30	\$		\$ 201

See notes to consolidated financial statements

F-6

---

**Table of Contents**

**OMEROS CORPORATION**

**NOTES TO THE 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 platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical and medical procedures. Our efforts are devoted to conducting research and development of our products, to developing our patent portfolio and to raising equity capital.

*Basis of Presentation*

Our consolidated financial statements include the financial position and results of operations of Omeros and nura, inc., or nura, our wholly owned subsidiary.

*Use of Estimates*

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

*Liquidity and Capital Resources*

We believe that our existing cash, cash equivalents and short-term investments and available capital under our at-the-market sales agreement and our committed equity line financing facility will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months. Our assumptions include our ability to raise capital under our \$60.0 million at-the-market sales agreement with MLV & Co. LLC, or MLV, and under our committed equity line financing facility with Azimuth Opportunity, Ltd., or Azimuth. Our Azimuth facility includes terms that limit the amount of committed proceeds we can raise in specified periods, which terms are described in Note 9. Because the Azimuth facility will expire on June 1, 2013, taking into account its limitations, we believe that the amount of committed proceeds that we could raise before June 1, 2013 would be significantly less than \$40.0 million. We are unable to estimate the actual amount as it depends on the price of our stock at the time we use the facility. If we do not raise additional capital, we may be required to delay, reduce the scope of, or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain products that we might otherwise seek to develop or commercialize independently, or enter into corporate collaborations at an earlier stage of development than we might otherwise choose.

We expect our continuing operating losses to result in an increasing total amount of cash used in operations over the next several years. To meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Except for our committed equity line financing facility with Azimuth which expires on June 1, 2013, we currently do not have any commitments for future external equity or debt funding. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. In addition, any future equity funding will dilute the ownership of our equity investors.

## **Table of Contents**

### *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 primarily 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, if necessary. 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. This evaluation is dependent 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 under a facility operating lease.

### *Property and Equipment*

Property and equipment are stated at cost. 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 are amortized over the shorter of the useful lives of the related assets or the lease term.

### *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 that the asset is expected to generate. If the asset is considered to be impaired, the amount of any impairment will be reflected in the result of operations in the period of impairment. We have not recognized any impairment losses.

### *Deferred Rent*

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



## **Table of Contents**

Our revenue relates to grant funding from third parties and revenue recognized in connection with funding from Vulcan Inc. and its affiliate, which we refer to collectively as Vulcan, and the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or LSDF, for our G protein-coupled receptor, or GPCR, program. We recognize such funds as revenue 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 and benefits; occupancy; clinical studies performed by third parties; materials and supplies to support our clinical programs; contracted research; manufacturing; related consulting arrangements; and other expenses incurred to sustain our overall research and development programs. Research and development expenses are expensed as incurred.

Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are 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 products. Patent application costs are expensed as incurred as a component of general and administrative expense, as recoverability of such expenditures is uncertain.

### *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. A valuation allowance is established when it is not more likely than not that the deferred tax assets will 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. The Black-Scholes model 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.

### *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.

**Table of Contents***Adoption of Standards*

In June 2011, the Financial Accounting Standards Board issued an Accounting Standards Update, or ASU, related to the presentation of comprehensive income that requires companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. It eliminated the option to present components of other comprehensive income as part of the statement of changes in shareholders' equity. The standard does not change the items that must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. This standard, which must be applied retroactively, was effective for interim and annual periods beginning after December 15, 2011. We adopted the standards on January 1, 2012 and now present a combined statement of operations and comprehensive loss in our accompanying financial statements.

**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. The net loss per share for the year ended December 31, 2012 reflects the issuance of 3,365,854 common shares issued in our public offering in the third quarter of 2012.

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 and the as if-converted method. The basic and diluted net loss per share amounts for the years ended December 31, 2012, 2011, and 2010 were computed based on the shares of common stock outstanding during the respective periods. Historical outstanding dilutive securities not included in the diluted loss per share calculation are as follows:

	Year Ended December 31,		
	2012	2011	2010
Outstanding options to purchase common stock	5,269,353	3,006,567	3,589,292
Warrants to purchase common stock	609,016	609,016	609,016
Total	5,878,369	3,615,583	4,198,308

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

As of December 31, 2012 and 2011, all investments are classified as short-term and available-for-sale on the accompanying balance sheets. We did not own any securities with unrealized loss positions as of December 31, 2012 or 2011. Investment income consists primarily of interest income.

**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.

**Table of Contents**

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

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

	Level 1	December 31, 2011		
		Level 2	Level 3	Total
		(in thousands)		
Assets:				
Money market mutual funds classified as cash equivalents	\$ 2,394	\$	\$	\$ 2,394
Money market mutual funds classified as current restricted cash	193			193
Money-market mutual funds classified as short-term investments	20,565			20,565
Total	\$ 23,152	\$	\$	\$ 23,152

Cash of \$1.5 million and \$1.6 million is excluded in our fair-value hierarchy disclosure as of December 31, 2012 and 2011, respectively. There were no unrealized gains and losses associated with our short-term investments as of December 31, 2012 or 2011.

**Note 5 Certain Balance Sheet Accounts***Receivables*

Grant and other receivables consisted of the following:

	December 31, 2012        2011 (in thousands)	
Grant and GPCR funding receivables	\$ 402	\$ 862
Lease incentives receivable	1,488	
Other receivables	44	14
<b>Grant and other receivables</b>	<b>\$ 1,934</b>	<b>\$ 876</b>

**Table of Contents***Property and Equipment*

Property and equipment consisted of the following:

	December 31,	
	2012	2011
	(in thousands)	
Computer equipment	\$ 394	\$ 490
Computer software	98	419
Office equipment and furniture	500	284
Leasehold improvements		304
Capital lease equipment	231	201
Laboratory equipment	1,603	1,520
<b>Total</b>	<b>2,826</b>	<b>3,218</b>
Less accumulated depreciation and amortization	(1,789)	(2,479)
<b>Property and equipment, net</b>	<b>\$ 1,037</b>	<b>\$ 739</b>

Our property and equipment have lives that range from three to ten years. For the years ended December 31, 2012, 2011 and 2010, depreciation expense was \$320,000, \$435,000 and \$472,000, respectively.

*Accrued Expenses*

Accrued expenses consisted of the following:

	December 31,	
	2012	2011
	(in thousands)	
Clinical trials	\$ 1,842	\$ 3,532
Contract research	1,447	694
Deferred rent	959	28
Employee compensation	458	364
Other accruals	1,010	722
<b>Accrued expenses</b>	<b>\$ 5,716</b>	<b>\$ 5,340</b>

*Accumulated Other Comprehensive Loss*

Comprehensive loss is comprised of net loss and certain changes in equity that are excluded from net loss. Our only component of other comprehensive loss is unrealized gains (losses) on available-for-sale securities. There was no accumulated other comprehensive loss as of December 31, 2012 as we sold the underlying available-for-sale securities in May 2010.

**Note 6 Notes Payable***Loan and Security Agreement*

In October 2010, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance LLC, or Oxford, pursuant to which Oxford agreed to lend us up to \$20.0 million in two tranches of \$10.0 million each. We borrowed the first tranche in October 2010, or Tranche 1, and the second tranche in March 2011, or Tranche 2. In December 2012, we entered into an amendment to the Loan Agreement, or the Amendment, pursuant to which we borrowed an additional \$7.2 million, or Tranche 3, and amended the repayment terms of the existing

outstanding indebtedness under Tranche 1 and Tranche 2. The Amendment

F-12

## **Table of Contents**

provides for interest-only payments on Tranche 1, Tranche 2 and Tranche 3 through December 31, 2013. Beginning on January 1, 2014, payments of principal and interest are payable for 36 months, in arrears. All unpaid principal and accrued and unpaid interest are due and payable on the maturity date, December 1, 2016. Our total outstanding principal to Oxford was \$20.0 million as of December 31, 2012. Interest on the outstanding \$20.0 million accrues at an annual fixed rate of 9.25%. We are using the proceeds from Tranche 3 for working capital and general business purposes.

Prior to the Amendment, upon borrowing Tranche 1 and Tranche 2, we recorded discounts on the loans related to final payment fees of \$500,000 and \$400,000, respectively, and we capitalized debt issuance costs in other assets of \$169,000 and \$58,000, respectively. Both the discount and the debt issuance costs were amortized to interest expense using the effective-interest method over the repayment term of the initial loan amount. In connection with the Amendment, we paid \$588,000 for the prorated portion of the final payments due under Tranche 1 and Tranche 2 with no further obligation for the remaining portion. We accounted for the Amendment as a debt modification rather than an extinguishment of debt. Accordingly, the remaining unamortized costs associated with the original debt will be amortized to interest expense using the effective-interest method over the amended repayment term.

In connection with the Amendment, we agreed to pay Oxford a final payment fee equal to 7.0% of the borrowed \$20.0 million, or \$1.4 million, which we recorded as a discount on the outstanding debt. We also capitalized in other assets \$168,000 in debt issuance costs that we incurred. Both of these amounts are being amortized to interest expense using the effective-interest method over the amended repayment term. As of December 31, 2012, unamortized discount and debt issuance costs associated with the modified debt was \$1.4 million and \$168,000, respectively.

We may prepay the outstanding principal balance in its entirety, plus accrued and unpaid interest, at any time upon delivery of prior notice to Oxford and the payment of a prepayment fee equal to 1.0% of the then-outstanding principal amount, which prepayment fee would be waived if we refinance the indebtedness with Oxford. As security for its obligations under the Loan Agreement, we granted Oxford a security interest in substantially all of our assets, excluding intellectual property. The Loan Agreement contains customary affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, 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, or repurchase stock, in each case subject to customary exceptions for a loan agreement of this size and type.

The Loan Agreement includes customary events of default that include, among other things, 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 our indebtedness to Oxford. Under certain circumstances, a default interest rate will apply on all obligations during the existence of an event of default under the Loan Agreement at a per annum rate equal to 5.0% above the otherwise applicable interest rate.

MAE is defined in the Loan Agreement as a material adverse effect upon (i) the 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 Loan Agreement, (ii) the validity, perfection, value or priority of Oxford's security interest in the collateral, (iii) the enforceability of any material provision of the Loan Agreement or related agreements or (iv) the ability of Oxford to enforce its rights and remedies under the Loan Agreement or related agreements. We considered the MAE definition and believe that the MAE clause has not been triggered as of December 31, 2012.

**Table of Contents***Equipment Financing*

We have capital leases for copier equipment, which have lease terms of 60 months. Equipment related to these capital leases of \$231,000 and \$201,000 is included in our property, plant and equipment as of December 31, 2012 and 2011, respectively. At December 31, 2012 and 2011, this equipment had a net book value of \$132,000 and \$144,000, respectively, which included \$99,000 and \$57,000 of accumulated depreciation, respectively.

*Future Principal Payments*

Future principal payments as of December 31, 2012 under the Loan Agreement and our copier leases, based on stated contractual maturities, are as follows:

<b>Year Ending December 31,</b>	<b>Total (in thousands)</b>
2013	\$ 47
2014	6,116
2015	6,683
2016	7,295
2017	5
Total principal payments	\$ 20,146

The principal payments reflected in the table above exclude the remaining unamortized balance of the debt discount and include the short-term portion of the principal payments on our copier leases, which are included in accrued liabilities in the accompanying balance sheet.

**Note 7 Revenue**

We have received Small Business Innovative Research, or SBIR, grants from the National Institutes of Health, or NIH, which are used to support the research and development of our products. We recorded revenue related to these grants of \$721,000, \$266,000 and \$876,000, for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, \$1.8 million remained available under these grants.

In December 2006, we entered into a funding agreement with The Stanley Medical Research Institute, or SMRI, to develop a proprietary phosphodiesterase 10, or PDE10, inhibitor product for the treatment of schizophrenia. We hold the exclusive rights to the technology. In consideration for SMRI's grant funding, we will become obligated to pay SMRI royalties based on net income, as defined under the agreement, from commercial sales of a PDE10 inhibitor product, not to exceed a set multiple of total grant funding received. If a PDE10 inhibitor product does not reach commercialization, we are not required to repay the grant funds. Through December 31, 2012, we have received a total of \$5.7 million from SMRI in the form of grant and equity funding. As of December 31, 2012, all amounts pertaining to this agreement previously recorded as deferred revenue in the accompanying balance sheet have been recognized as revenue. We recognized revenue under the SMRI funding agreement of \$0, \$227,000 and \$475,000, for the years ending December 31, 2012, 2011, and 2010, respectively. See additional discussion of the SMRI agreement under Note 8.

In October 2010, we entered into a platform development funding agreement with Vulcan pursuant to which we received \$20.0 million for our GPCR program. Of the funds received from Vulcan, we recorded \$10.8 million as a reduction of the cost of the intellectual property assets we purchased from Patobios Limited, or Patobios, \$994,000 was recorded in equity for the fair value of warrants issued to Vulcan, and the remaining \$8.2 million was recorded as deferred revenue. The deferred revenue balance is being recognized as revenue or as a reduction to the costs of assets purchased in direct proportion to the related GPCR expenses as they are incurred. Also in October 2010, we entered into an agreement with LSDF under which we received a \$5.0 million grant award.

## **Table of Contents**

from LSDF that was paid to reimburse us for expenses we incurred and equipment purchases related to our GPCR program. For the years ended December 31, 2012, 2011 and 2010, we have recorded reductions to the Vulcan deferred revenue balance of \$4.7 million, \$2.0 million and \$484,000 respectively, which includes \$4.7 million, \$2.0 million and \$468,000 recognized as revenue and \$60,000, \$38,000 and \$16,000 recorded as cost reductions to assets, respectively. As of December 31, 2012, \$970,000 in deferred revenue pertaining to the Vulcan agreement was recorded in the accompanying balance sheet. We recognized all remaining revenue under the LSDF agreement during the first quarter of 2012. For the years ended December 31, 2012, 2011 and 2010, respectively, we recognized revenue of \$624,000, \$2.0 million, and \$212,000 and have recorded cost reductions to assets of \$0, \$1.7 million and \$494,000. See additional discussion of the Vulcan and LSDF agreements under Note 8.

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

In connection with the funding agreement with SMRI, beginning the first calendar year after commercial sales of a schizophrenia product, if and when a product is commercialized, we may become obligated to pay royalties based on net income, as defined in the agreement, not to exceed a set multiple of total grant funding received. Based on the amount of grant funding received as of December 31, 2012, the maximum amount of royalties payable by us is \$12.8 million. We have not paid any such royalties through December 31, 2012.

In February 2009, we entered into a patent assignment agreement with an individual whereby we acquired all intellectual property rights, including patent applications, related to peroxisome proliferators activated receptor gamma, or PPAR $\gamma$ , agonists for the treatment and prevention of addictions to substances of abuse, as well as other compulsive behaviors. No payments were made related to the technology acquisition. 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. Under the agreement, we will be required to make payments of up to \$3.8 million in total, for both PPAR $\gamma$  agonists and dietary supplements that increase PPAR $\gamma$  activity, to the individual 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 any patents that issue from the acquired patent application.

In March 2010, we entered into a license agreement with Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.), or Daiichi Sankyo, pursuant to which we received an exclusive license to phosphodiesterase 7, or PDE7, inhibitors claimed in certain patents and pending patent applications owned by Daiichi Sankyo for use in the treatment of movement disorders and other specified indications. In February 2011, we amended the agreement to include addiction and compulsive disorders in the field of use. In January 2013, we amended the agreement to include all other indications except specified dermatologic conditions. Upon execution of the agreement, we made a one-time payment to Daiichi Sankyo of \$50,000 that was recognized as research and development expense. Under the amended agreement, we agreed to make milestone payments to Daiichi Sankyo of up to \$33.5 million upon the achievement of certain events, such as 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 that we receive from the sublicensee.

In April 2010, we entered into an exclusive license agreement with Helion Biotech ApS, or Helion, pursuant to which we received a royalty bearing, worldwide exclusive license in and to all of Helion's intellectual property rights related to mannan-binding lectin-associated serine protease-2, or 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. Upon execution of the agreement, we made a one-



## **Table of Contents**

time payment to Helion of \$500,000 that was recognized as research and development expense and agreed to make development and sales milestone payments to Helion of up to an additional \$6.9 million upon the achievement of certain events, such as the filing of an Investigational New Drug application with the U.S. Food and Drug Administration; initiation of Phase 2 and 3 clinical trials; receipt of marketing approval; and reaching specified sales milestones. In addition, Helion is entitled to receive from us a low single-digit percentage royalty of any net sales of a MASP2 inhibitor product that is covered by the patents licensed by us under the agreement.

In connection with our funding agreements with Vulcan and LSDF discussed in Note 7, we have agreed to pay Vulcan and LSDF tiered percentages of the net proceeds, if any, derived 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. Pursuant to the agreement with Vulcan, at our option, we may pay a portion of Vulcan's share of the one percent of net proceeds to a life sciences initiative, or 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 defined in the Vulcan and LSDF agreements as (1) all consideration received by us in any form relating directly to the GPCR program, such as from license fees, milestone fees, royalties, product sales, partnerships and a transfer of the GPCR program to a third party, subject to exceptions specified in such agreements, less (2) all expenses and expenditures in excess of \$25.0 million incurred by us in connection with the GPCR program such as for research and development, related overhead, milestone and royalty payments, legal expenses, cost of goods sold and product sales deductions. 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.

In November 2010, pursuant to our agreement with Vulcan, we purchased from Patobios intellectual property assets related to an assay technology for use in the GPCR program. We also issued to Vulcan three warrants to purchase our common stock, each with a five-year term and exercisable for 133,333 shares, with exercise prices of \$20, \$30 and \$40 per share, respectively. The exercise price of the warrants may be paid in cash or on a cashless basis in which the number of shares issuable upon exercise of the warrant would be reduced by the number of shares having a fair market value equal to the applicable exercise price. 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.

Under our agreement with LSDF, after LSDF receives \$25.0 million from us, any remaining amounts that would be payable by us to LSDF pursuant to the agreement will instead 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. We have no other obligations, funding or otherwise, to LSI. 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.

## **Table of Contents**

Effective October 26, 2012, Omeros Corporation, Gregory A. Demopoulos, M.D., our chairman, chief executive officer, president and interim chief financial officer, and Richard J. Klein, our former chief financial officer and treasurer, entered into the Settlement Agreement settling and releasing all of the parties' respective claims in the lawsuit described in Part II, Item 1 of our Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission 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 Qui Tam Claims were dismissed without prejudice to the United States Government.

In the Settlement Agreement, each of the parties affirmatively denies any wrongdoing or liability. In addition, the Settlement Agreement bars Mr. Klein and his attorneys from seeking any personal recovery or attorneys' fees for the Qui Tam Claims. Under the terms of the Settlement Agreement, we made a one-time payment of \$3.94 million to Mr. Klein to release all of his claims, which included a claim for payment of his attorneys' fees since 2009 incurred in connection with the lawsuit. In 2012, we recorded \$3.95 million as litigation settlement on the accompanying statements of operations and comprehensive loss.

Carolina Casualty Insurance Company, or CCIC, was the carrier for our directors, officers and corporate liability insurance policy in effect at the time Mr. Klein's employment with us was terminated. On February 21, 2012, CCIC filed a complaint for a declaratory judgment against Omeros, Dr. Demopoulos and Mr. Klein in the U.S. District Court for the Western District of Washington, seeking a declaration that CCIC owes no duty to indemnify or defend Omeros or Dr. Demopoulos against the allegations raised by Mr. Klein. On May 10, 2012, 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.

CCIC paid, in part, our defense costs associated with Mr. Klein's lawsuit, subject to a reservation of rights, and we paid the remaining portion of the defense costs. Additionally, on November 19, 2012 CCIC reimbursed us \$3.95 million for the \$3.94 million payment we made to Mr. Klein under the terms of the Settlement Agreement as well as related employment taxes we paid of approximately \$13,000. During the quarter ended December 31, 2012, we recorded \$3.95 million as a recovery on settlement on the accompanying statements of operations and comprehensive loss. CCIC made this payment without waiving any of its rights, including a potential claim seeking recovery of the \$3.95 million, and without affecting any of our or our chief executive officer's counterclaims, including for failure to defend and bad faith, against CCIC in the pending lawsuit against CCIC. As of March 18, 2013, CCIC has not amended its complaint to seek such recovery, but may choose to do so in the future. We are vigorously defending the declaratory judgment action and pursuing our counterclaims, we will vigorously defend any attempt by CCIC to recover the \$3.95 million, and we do not believe any such recovery attempt by CCIC would succeed. While we can provide no assurances regarding the outcome of the litigation with CCIC, we believe that CCIC is required under the insurance policy to defend and indemnify us in the Klein litigation, including for the \$3.95 million in costs we incurred under the Settlement Agreement. In addition, while we can provide no assurances, we also believe that CCIC acted unreasonably and in bad faith, and unreasonably denied a claim for coverage in violation of Washington law. While the ultimate financial impact of this action cannot be determined with certainty, based on analysis, we believe that we will not be required to return the amounts paid by CCIC in November 2012. Therefore, no loss associated with the CCIC actions has been recorded in the financial statements as of December 31, 2012.

In January 2012, we entered into the Lease with BMR-201 Elliott Avenue LLC, or BMR, pursuant to which we lease 64,483 square feet of office and laboratory spaces in The Omeros Building. The initial term of the Lease is 15 years with two options to extend the lease term, each by five years. The lease term commenced in November 2012. The aggregate rent payable under the initial term of the Lease is approximately \$51.1 million, with no annual base rent due during the first year. The Lease required us to provide the landlord with \$563,000 as a security deposit, which is recorded as restricted cash on the accompanying balance sheet as of December 31,

**Table of Contents**

2012. Additionally, on March 30, 2012 the landlord paid us a \$3.0 million cash lease incentive and the landlord has agreed to reimburse us for up to \$650,000 in expenses incurred by us in connection with the leased premises, of which we had incurred \$602,000 as of December 31, 2012.

In November 2012, we entered into the First Amendment to the Lease, or the Amendment, pursuant to which we will lease an additional 13,363 square feet in The Omeros Building, or the Additional Premises. The lease term for the Additional Premises is expected to commence by May 2013 and will end in November 2027, coterminous with the term of the Lease. The aggregate rent payable under the initial term of the Amendment is approximately \$10.6 million. The Amendment required us to pay an additional \$117,000 as a security deposit.

In November 2012, we entered into the Second Amendment to the Lease, or the Second Amendment, pursuant to which we will lease an additional 5,177 square feet in The Omeros Building, or the Additional Vivarium Premises. The lease term for the Additional Vivarium Premises commenced in November 2012 and will end in November 2027, coterminous with the term of the Lease. The aggregate rent payable under the initial term of the Amendment is approximately \$5.8 million. We are subleasing all of the Additional Vivarium Premises.

As of December 31, 2012, we recorded as deferred rent a net amount of \$4.6 million related to the lease incentives and direct costs incurred in connection with consummating the Lease, as amended. The short-term and long-term portions of the deferred rent were recorded in accrued expenses and other non-current liabilities, respectively, and will be amortized over the initial term of the Lease.

In January 2012, in connection with the new lease agreement for The Omeros Building, we gave notice to the landlord of our prior corporate office space that we were terminating the lease for that space on January 30, 2013. In September 2012, we entered into an amendment of our lease with the landlord of our then-current corporate office space to provide for the termination of that lease on November 30, 2012. Additionally, as the lease for our lab facilities terminated on September 30, 2012, we incurred holdover penalties of \$206,000, which were reimbursed to us by BMR as provided under the Lease, and recorded to deferred rent as a lease incentive.

Rent expense totaled \$2.9 million, \$2.2 million and \$2.1 million for the years ended December 31, 2012, 2011 and 2010, respectively. Rental income received under subleases was \$635,000, \$693,000 and \$793,000 for the years ended December 31, 2012, 2011 and 2010, respectively. Rental income is recorded as other income in the consolidated statements of operations and comprehensive loss.

We lease laboratory and corporate office space and rent equipment under operating lease agreements that include certain rent escalation terms. We sublease approximately 5,179 square feet of our leased properties. Future minimum payments related to the leases, which exclude common area maintenance and related operating expenses, at December 31, 2012, are as follows:

Year Ending December 31,	Lease Payments	Sublease Income (in thousands)	Net Lease Payments
2013	510	550	(40)
2014	3,193	550	2,643
2015	3,936	550	3,386
2016	4,026	550	3,476
2017	4,119	480	3,639
Thereafter	45,928		45,928
<b>Total</b>	<b>\$ 61,712</b>	<b>\$ 2,680</b>	<b>\$ 59,032</b>

**Table of Contents****Note 9 Shareholders Equity***Common Stock*

In December 2012, we entered into an at-the-market issuance sales agreement, or the Sales Agreement, with MLV pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to \$60.0 million directly on The NASDAQ Global Market or sales made to or through 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% 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 shares under the Sales Agreement, or, if we do, 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 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 addition, the Sales Agreement will automatically terminate upon the sale of all common stock subject to the Sales Agreement. Any sales of shares of common stock pursuant to the Sales Agreement will be made under our previously filed and currently effective shelf registration statement on Form S-3 and the related prospectus supplement dated and filed on December 14, 2012.

In May 2011, we entered into a committed equity line financing facility with Azimuth pursuant to which we are permitted to sell up to \$40.0 million of our shares of common stock over a 24-month term. This facility replaced a prior committed equity line financing facility with Azimuth. Under our agreement with Azimuth, we may, from time to time over the 24-month term and in our sole discretion, present Azimuth with draw down notices requiring Azimuth to purchase a specified dollar amount of shares of our common stock, based on the volume-weighted average price per share on each of 10 consecutive trading days, or the draw down period, with the total dollar amount of each draw down subject to certain agreed-upon limitations based on the market price of our common stock at the time of the draw down. The purchase price for these shares equals the daily volume-weighted average price of our common stock on each date during the draw down period on which shares are purchased, less a discount ranging from 3.00% to 6.00%, based on a minimum price that we specify. We are allowed to present Azimuth with up to 24 draw down notices during the 24-month term, with only one such draw down notice allowed per draw down period and a minimum of five trading days required between each draw down period. We may not issue more than 4,427,562 shares in connection with the committed equity line financing facility, although this limitation does not apply if the average purchase price of all shares issued to Azimuth, taking into account all discounts, equals or exceeds \$5.02 per share, which amount is subject to adjustment in certain circumstances specified in the facility. We have not drawn funds under this facility to date and it will expire on June 1, 2013 unless we and Azimuth mutually agree to extend it. Because the facility will expire on June 1, 2013, taking into account its limitations described above, we believe that the amount of committed proceeds that we could raise before June 1, 2013 would be significantly less than \$40.0 million. We are unable to estimate the actual amount as it depends on the price of our stock at the time we use the facility.

In connection with this facility, we entered into a placement agent agreement with Reedland Capital Partners, an Institutional Division of Financial West Group, member FINRA/SIPC, or FWG/Reedland. We have agreed to pay FWG/Reedland, upon each sale of our common stock to Azimuth under the equity line financing facility, a fee equal to 0.5% of the aggregate dollar amount of common stock purchased by Azimuth.

As of December 31, 2012, we had reserved shares of common stock for the following purposes:

Options granted and outstanding	5,390,582
Options available for future grant	884,578
Common stock warrants	609,016
 Total shares reserved	 6,884,176

## **Table of Contents**

### *Public Offering*

In July 2012, we completed a public offering pursuant to which we sold 3,365,854 shares of our common stock at a price of \$10.25 per share. After deducting underwriting discounts and other offering expenses of \$2.2 million, we received net proceeds from the transaction of \$32.3 million.

### *Warrants*

In October 2010, in connection with the Vulcan agreement, we issued to Vulcan 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 exercise price of the warrants may be paid in cash or on a cashless basis in which the number of shares issuable upon exercise of the warrant would be reduced by the number of shares having a fair market value equal to the applicable exercise price. The warrants will expire on October 21, 2015. The fair value of the warrants included in equity was \$994,000 determined using the Black-Scholes option-pricing model.

On March 28, 2012, we extended by one year the expiration dates of warrants to purchase up to an aggregate of 197,478 shares of our common stock at an exercise price of \$12.25 per share. As a result of the extension, the expiration date of these warrants has been changed to March 29, 2013. We originally issued the warrants on March 29, 2007 to brokers who assisted us in connection with our Series E Preferred Stock financing. Pursuant to accounting guidance regarding equity-based compensation to non-employees, we evaluated the value of the warrants before and after the modification date to determine the incremental change in their fair value and recorded a change in fair value of \$511,000 in other expense. As of December 31, 2012, 2011 and 2010 we had outstanding warrants to purchase 609,016 shares of common stock with weighted-average exercise prices of \$23.85 per share.

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

### *Stock Options*

Our 2008 Equity Incentive Plan, or 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, or 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 subject to a maximum limit of 3,084,848 shares. As of December 31, 2012 a total of 365,696 shares have been reserved under the 2008 Plan as a result of the cancellation of options or repurchase of shares under the 1998 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 lesser 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, 2013 and 2012, in accordance with the 2008 Plan annual increase provisions, the authorized shares in the 2008 Plan increased by 1,294,874 and 1,121,511 shares, respectively. As of December 31, 2012, a total of 4,540,384 shares were reserved for issuance under the 2008 Plan. 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 ten 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. As stock-based compensation

**Table of Contents**

expense is based on options ultimately expected to vest, the expense has 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 years ended:

	December 31,		
	2012	2011	2010
Estimated weighted-average fair value	\$ 7.35	\$ 3.31	\$ 4.34
<b>Weighted-Average Assumptions</b>			
Expected volatility (A)	86%	83%	77%
Expected term, in years (B)	5.77	5.73	6.08
Risk-free interest rate (C)	0.95%	1.97%	2.55%
Expected dividend yield (D)	0%	0%	0%

- (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, 2012, 2011 and 2010, we granted to non-employees options to purchase 28,000, 15,000 and 9,600 shares of common stock, respectively.

*Stock-Based Compensation Summary.* Stock-based compensation expense includes amortization of stock options granted to employees and non-employees and has been reported in our consolidated statements of operations and comprehensive loss as follows:

	Year Ended December 31,		
	2012	2011	2010
	(in thousands)		
Research and development	\$ 2,191	\$ 819	\$ 971
Selling, general and administrative	2,090	1,108	1,207
<b>Total</b>	<b>\$ 4,281</b>	<b>\$ 1,927</b>	<b>\$ 2,178</b>

In connection with the non-employee options, we recognized expense of \$64,000, \$62,000 and \$139,000 during the years ended December 31, 2012, 2011 and 2010, respectively.

**Table of Contents**

Stock option activity and related information is as follows:

	<b>Options Outstanding</b>	<b>Weighted- Average Exercise Price per Share</b>	<b>Remaining Contractual Life (in years)</b>	<b>Aggregate Intrinsic Value (in thousands)</b>
Balance at December 31, 2011	3,006,567	\$ 3.32		
Granted	2,561,100	7.36		
Exercised	(101,395)	3.64		
Forfeited	(75,690)	6.90		
Balance at December 31, 2012	5,390,582	\$ 5.18	7.24	\$ 8,223
Vested and expected to vest at December 31, 2012	5,175,822	\$ 5.08	7.16	\$ 8,151
Exercisable at December 31, 2012	3,158,616	\$ 3.41	5.87	\$ 7,521

The total intrinsic value of options exercised during the years ended December 31, 2012, 2011, and 2010 was \$578,000, \$2.1 million and \$1.4 million, respectively.

Information about stock options outstanding and exercisable is as follows:

	<b>Options Outstanding</b>			<b>Options Exercisable</b>	
	<b>Number of Options</b>	<b>Weighted- Average Remaining Contractual Life (Years)</b>	<b>Weighted- Average Exercise Price</b>	<b>Number of Options</b>	<b>Weighted- Average Exercise Price</b>
<b>Range of Exercise Price</b>					
\$0.78-3.95	1,771,792	4.08	\$ 1.22	1,767,210	\$ 1.21
\$4.10-\$6.42	1,986,249	8.26	5.03	1,097,120	5.31
\$7.29-10.19	497,956	8.80	7.89	113,486	7.89
\$10.40-13.49	1,134,585	9.72	10.45	180,800	10.51
\$0.78-13.49	5,390,582	7.24	\$ 5.18	3,158,616	\$ 3.41

At December 31, 2012 there were 2,231,966 unvested options outstanding that will vest over a weighted-average period of 2.8 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these shares is \$10.1 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.

**Table of Contents**

Significant components of deferred tax assets are as follows:

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(in thousands)</b>	
Deferred tax assets:		
Net operating loss carryforwards	\$ 59,124	\$ 48,901
Deferred revenue		14
Stock-based compensation	2,183	1,306
Research and development tax credits	3,775	3,560
Investment in Partnership	1,389	547
Other	1,804	303
	68,275	54,631
Less valuation allowance	(68,275)	(54,631)
Net deferred tax assets	\$	\$

As of December 31, 2012 and 2011, we had net operating loss carryforwards of approximately \$173.9 million and \$143.8 million, respectively, and research and development tax credit carryforwards of approximately \$3.8 million and \$3.6 million, respectively. Unless previously utilized, our net operating loss and research and development tax credit carryforwards expire between 2013 and 2032.

In certain circumstances, due to ownership changes, the net operating loss and tax credit carryforwards may be subject to limitations under the Internal Revenue Code of 1986, as amended, or the Code. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event that a change in ownership, as defined in Section 382 of the Code, has occurred or may occur in the future. Approximately \$2.8 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.

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 \$13.6 million, \$9.5 million and \$11.1 million in 2012, 2011 and 2010, respectively, primarily due to net operating losses incurred during these periods.

Deferred tax assets do not include 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 3, 2013, which retroactively extended the research and development credit back to January 1, 2013. Accounting Standards Codification 740 requires the effect of tax legislation to be taken into account in the interim period in which the law was enacted. Therefore, the 2012 credits are not contained in the deferred tax assets for the 2012 period but will be included in the 2013 period.

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

	<b>December 31,</b>		
	<b>2012</b>	<b>2011</b>	<b>2010</b>
Statutory tax rate	(34)%	(34)%	(34)%
Permanent difference	2	1	(1)
Change in valuation allowance	35	33	27
Other	(3)		8
Effective tax rate			



**Table of Contents**

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 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, 2012, 2011 and 2010. 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.

Our policy is to 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.

We do not anticipate that our unrecognized tax benefits will significantly increase in the next 12 months.

**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 2012 and 2011 (in thousands, except per share amounts):

	March 31,	June 30,	September 30,	December 31,
			2012	
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)
			2011	
Revenue	\$ 1,239	\$ 1,155	\$ 987	\$ 1,143
Total operating expenses	7,689	6,104	7,151	10,990
Loss from operations	(6,450)	(4,949)	(6,164)	(9,847)
Net loss	(6,542)	(5,291)	(6,512)	(10,201)
Basic and diluted net loss per share	\$ (0.30)	\$ (0.24)	\$ (0.29)	\$ (0.46)

Operating expenses for the three-month period ended September 30, 2012 includes \$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.

**Table of Contents**

**EXHIBIT INDEX**

**Description**

dated April 26, 2005 (assumed by Omeros Corporation on August 11, 2006)
ation and holders of capital stock dated October 15, 2004
2012, warrants in this form were issued to purchase up to a total of 167,885 shares of common stock)
2012, warrants in this form were issued to purchase up to a total of 29,593 shares of common stock)
urchase Warrants filed as Exhibits 4.4 and 4.5)
urchase Warrants to March 29, 2013 (applicable to Stock Purchase Warrants filed as Exhibits 4.4 and 4.5)
vestment Holdings LLC, which warrants were subsequently assigned to its affiliate Vulcan Capital Venture Capital II LLC (as of December 31, 2012, warrants in this
on and its directors and officers
1998 Stock Option Plan (that does not permit early exercise)
an (used for option awards granted after October 7, 2009)
an (used for option awards granted on or before October 7, 2009)
orporation and Gregory A. Demopoulos, M.D. dated April 7, 2010
August 16, 2001
A. Demopoulos, M.D. dated June 16, 1994

---

**Table of Contents**

**Description**

Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated June 16, 1994	
Second Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopoulos, M.D. dated December 11, 2001	
Second Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated March 22, 2002	
Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopoulos, M.D. dated June 16, 1994 (related to tendon splice technology)	
Lease dated January 27, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	
First Amendment to Lease dated November 5, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	
Second Amendment to Lease dated November 16, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	
Fourth Amendment to Office Lease dated September 27, 2012 between Omeros Corporation and City Centre Associates	
Amended and Restated Settlement Agreement effective as of October 26, 2012 among Omeros Corporation, Gregory A. Demopoulos, M.D. and Richard J. Klein	
Commercial Supply Agreement between Omeros Corporation and Hospira Worldwide, Inc. dated October 9, 2007	
Exclusive License and Sponsored Research Agreement between Omeros Corporation and the University of Leicester dated June 10, 2004	
Research and Development Agreement First Amendment between Omeros Corporation and the University of Leicester dated October 1, 2005	
Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005	
Amendment dated May 8, 2007 to Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005	
Funding Agreement between Omeros Corporation and The Stanley Medical Research Institute dated December 18, 2006	
Patent Assignment Agreement between Omeros Corporation and Roberto Ciccocioppo, Ph.D. dated February 23, 2009	
First Amendment to Patent Assignment Agreement between Omeros Corporation and Roberto Ciccocioppo, Ph.D. effective December 31, 2010	
Omeros Corporation Non-Employee Director Compensation Policy	
License Agreement between Omeros Corporation and Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.) dated March 3, 2010	
Amendment No. 1 to License Agreement with an effective date of January 5, 2011 between Omeros Corporation and Daiichi Sankyo Co., Ltd.	
Amendment No. 2 to License Agreement with an effective date of January 25, 2013 between Omeros Corporation and Daiichi Sankyo Co., Ltd.	

**Table of Contents**

**Description**

Omeros Corporation and Helion Biotech ApS dated April 20, 2010

ated May 10, 2011 between Omeros Corporation and Azimuth Opportunity, Ltd.

between Omeros Corporation and Reedland Capital Partners, an Institutional Division of Financial West Group, member FINRA/SIPC

ated December 14, 2012 between Omeros Corporation and MLV & Co. LLC

October 21, 2010 between Omeros Corporation and Oxford Finance LLC (successor-in-interest to Oxford Finance Corporation)

and Security Agreement dated February 3, 2011 between Omeros Corporation and Oxford Finance LLC (successor-in-interest to Oxford Finance Corporation)

ity Agreement dated March 25, 2011 between Omeros Corporation and Oxford Finance LLC (successor-in-interest to Oxford Finance Corporation)

y Agreement dated June 13, 2011 between Omeros Corporation and Oxford Finance LLC

ty Agreement dated February 1, 2012 between Omeros Corporation and Oxford Finance LLC

Agreement dated June 23, 2012 between Omeros Corporation and Oxford Finance LLC

y Agreement dated December 28, 2012 between Omeros Corporation, Oxford Finance LLC and Oxford Finance Funding Trust 2012-01

r 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)

ecured 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)

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)

ecured 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)

ber 28, 2012 with a principal amount of \$4,000,000 issued by Omeros Corporation to Oxford Finance LLC

ber 28, 2012 with a principal amount of \$3,176,303 issued by Omeros Corporation to Oxford Finance LLC

ment between Omeros Corporation and Vulcan Inc. and its affiliate dated October 21, 2010

## **Table of Contents**

### **Description**

ard Agreement between Omeros Corporation and the Life Sciences Discovery Fund Authority dated October 21, 2010

arnings to Fixed Charges

f Independent Registered Public Accounting Firm

on 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 Sar

on 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 Sarb

on 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

on 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

istance Document

xonomy Extension Schema Document

xonomy Extension Calculation Linkbase Document

xonomy Extension Definition Linkbase Document

xonomy Extension Labels Linkbase Document

xonomy 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).

**Table of Contents**

- (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).
- \* 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.