

OMEROS CORP  
Form 10-K  
March 15, 2011  
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**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, 2010**

or

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

**For the transition period from                      to**

Commission file number: 001-34475

**OMEROS CORPORATION**

(Exact name of registrant as specified in its charter)

Washington  
(State or other jurisdiction of incorporation or organization)

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

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1420 Fifth Avenue, Suite 2600

Seattle, Washington  
(Address of principal executive offices)

(206) 676-5000

98101  
(Zip Code)

(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 ☐ Smaller reporting company ☐  
(Do not check if a 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 \$143,362,525. 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 10, 2011, 22,137,182 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 2011 Annual Meeting of Shareholders to be held May 27, 2011, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2010, are incorporated by reference into Part III of this Form 10-K.

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*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 end of Item 1 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, bleeding and disorders of the central nervous system. Our most clinically advanced product candidates are derived from our proprietary PharmacoSurgery™ platform designed to improve clinical outcomes of patients undergoing arthroscopic, ophthalmological, 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 six ongoing clinical development programs, including four from our PharmacoSurgery platform and two from our addiction franchise. Our most advanced clinical development program is in a Phase 3 clinical program evaluating OMS103HP for arthroscopy in patients undergoing arthroscopic anterior cruciate ligament, or ACL, reconstruction. We expect to announce data from this program during the first quarter of 2011. 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 product candidates and programs, we have retained all manufacturing, marketing and distribution rights.

**Our Product Candidates and Development Programs**

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

Program	Targeted		Next Expected		Worldwide
	Procedure/Disease	Development Status	Milestone	Rights	
<b>Clinical Programs</b>					
OMS103HP Arthroscopy	Arthroscopic ACL reconstruction	Phase 3	Announce Phase 3 trial results	Omeros	
OMS103HP Arthroscopy	Arthroscopic meniscectomy	Phase 3	Begin Phase 3 trials	Omeros	
OMS302 Ophthalmology	Cataract surgery	Phase 2b	Announce Phase 2b trial results	Omeros	
OMS201 Urology	Ureteroscopy	Phase 1/2	Design Phase 2 trial	Omeros	
PPARg Addiction	Prescription opioid addiction	Phase 2	Complete Phase 2 trial	Omeros	
PPARg Addiction	Heroin addiction	Phase 2	Complete Phase 2 trial	Omeros	
<b>GPCR Program</b>	Multiple disorders	Platform	Continue drug discovery for orphan GPCRs	Omeros	
<b>Preclinical Programs</b>					
Plasmin	Surgical and traumatic bleeding	Preclinical	Complete IND-enabling studies	Omeros (In-licensed)	
PDE7	Addictions and compulsive disorders; movement disorders	Preclinical	Complete IND-enabling studies	Omeros	
MASP-2	Macular degeneration, ischemia-reperfusion injury, transplant surgery, radiation injury	Preclinical	Complete IND-enabling studies	Omeros (In-licensed)	
PDE10	Schizophrenia	Preclinical	Complete IND-enabling studies	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 product candidates 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 product candidates are added to standard surgical irrigation solutions and delivered intra-operatively 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, we believe that the clinical benefits of our product candidates 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 product candidates are specifically comprised of active pharmaceutical ingredients, or APIs, contained in generic drugs already approved by the 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.

***OMS103HP Arthroscopy***

*Background.* OMS103HP is our PharmacoSurgery product candidate being developed for use during arthroscopic procedures, including ACL reconstruction surgery and 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.

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. Minimizing postoperative inflammation and pain may not only decrease the time to return to work and to activities of daily living, but also could decrease arthrofibrosis and other postoperative complications. Arthrofibrosis is a complication caused by surgical trauma in which excessive scar tissue forms within the joint and surrounding soft tissue spaces resulting in pain, restricted joint motion and loss of function.

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The inflammation associated with arthroscopic surgery, or any other procedure resulting in tissue trauma, is a complex reaction to tissue injury with multiple pathways, mechanisms and pro-inflammatory mediators, such as PGE2, involving three major components:

alterations in vascular caliber, or vasodilation, that lead to an increase in blood flow;

structural changes in the microvasculature that permit plasma proteins to leave the circulation, or plasma extravasation; and

white cell migration from the microcirculation to the site of tissue injury.

The key cellular events involved in these components include the synthesis and release of multiple pro-inflammatory mediators. Consequently, multiple pharmacologic actions are required to manage the complexity and inherent redundancy of the inflammatory cascade.

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. OMS103HP contains the following three APIs, each of which is known to interact with different, discrete molecular targets that are involved in the acute inflammatory and pain response:

*Ketoprofen*, a non-steroidal anti-inflammatory drug, or NSAID, is a non-selective inhibitor of the pro-inflammatory mediators COX-1 and COX-2, with potent anti-inflammatory and analgesic actions that result from inhibiting the synthesis of the pro-inflammatory mediator PGE2, and antagonizing the effects of bradykinin, another inflammatory mediator;

*Amitriptyline* is a compound with analgesic activity that inhibits the pro-inflammatory actions of histamine and serotonin released locally at the site of tissue trauma; and

*Oxymetazoline* is a vasoconstrictor and also activates serotonin receptors, located on a group of nerve fibers called primary afferents, that can inhibit the release of proinflammatory mediators such as substance P and calcitonin gene-related peptide, or CGRP.

In combination, these APIs inhibit PGE2 production, decrease inflammation-induced vasodilation and prevent increased vascular permeability, as well as block the release of proinflammatory mediators from primary afferent nerve endings, or neurogenic inflammation, at the site of surgical trauma. Using an in vivo joint model of acute inflammation-induced plasma extravasation, preclinical studies showed that the combined activity of all three APIs in OMS103HP produced significant inhibition of plasma extravasation and was more effective than any of the two-API combinations or any single API administered alone, demonstrating that each API contributed to the effect of OMS103HP.

*Market Opportunity.* According to SOR Consulting, approximately a total of: 4.0 million arthroscopic operations were performed in the United States in 2006, including 2.6 million knee arthroscopy operations. Based on independent reports that we commissioned from The Reimbursement Group, or TRG, and from Musculoskeletal Clinical Regulatory Advisers, we believe that OMS103HP will be favorably reimbursed both to the surgical facility for its utilization and to the surgeon for its administration and delivery. We believe that OMS103HP will, if approved, be the first commercially available drug delivered directly to the surgical site to improve function following arthroscopic surgery. Also, use of OMS103HP does not require a surgeon to change his or her operating procedure. In addition to ease of use, we believe that the clinical benefits of OMS103HP 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.

*Clinical Trial Results ACL Reconstruction.* We conducted a double-blind, vehicle-controlled, parallel-group, randomized Phase 1/Phase 2 clinical trial of OMS103HP in a total of 35 patients undergoing arthroscopic cadaveric, or allograft, ACL reconstruction surgery. 34 patients comprised the intent to treat population, 18 patients in the OMS103HP group and 16 patients in the vehicle group. 30 patients, 14 OMS103HP and 16



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vehicle patients, were included in the efficacy evaluable population. The intent-to-treat population consisted of all patients who were randomized into the study, received OMS103HP or vehicle control, and had at least one recovery room evaluation. The OMS103HP and vehicle groups showed no significant differences in demographics, or pre- or intra-operative findings. Patients were adults scheduled to undergo primary ACL reconstruction surgery, using patellar tendon-bone or Achilles tendon allografts, for an ACL tear occurring from two weeks to one year prior to the day of arthroscopic surgery. Patients were followed for 30 postoperative days and instructed to complete a patient diary each day.

Efficacy endpoints included assessments of range of motion, knee function, pain management, quadriceps and hamstring muscle strength, and return to work. Assessments were collected during clinic and rehabilitation visits and in the patient diary. At each clinic visit a visual analog scale, or VAS, pain score was obtained and passive range of motion measurements were taken. At the end of the 30-day evaluation period, physical and orthopedic examinations were also performed and quadriceps and hamstring strength testing was conducted. At each study rehabilitation visit, knee function and range of motion were assessed. Patients treated with OMS103HP demonstrated statistically significant: (1) improvement in postoperative knee range of motion, (2) improvement in postoperative knee function, (3) better pain management and (4) earlier return to work. No adverse events were determined to be related to the delivery of OMS103HP and there was no evidence of OMS103HP having any detrimental effect with respect to healing, either in soft tissue or bone.

The results of this Phase 1/Phase 2 clinical program were published in a peer-reviewed article titled "Novel Drug Product to Improve Joint Motion and Function and Reduce Pain After Arthroscopic Anterior Cruciate Ligament Reconstruction" that appeared in the June 2008 issue of *Arthroscopy: The Journal of Arthroscopic and Related Surgery* (Vol. 24, No. 6: pp. 625-636).

**Clinical Trial Results Meniscectomy.** We conducted 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. 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 subjects (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 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," has been accepted for publication in the peer-reviewed *Arthroscopy: The Journal of Arthroscopic and Related Surgery*.

Although these positive results from our clinical studies 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 two clinical programs. The first is a Phase 3 program evaluating OMS103HP's safety and ability to improve postoperative joint function and reduce pain following ACL reconstruction surgery. This Phase 3 program consists of three multi-center trials, two evaluating efficacy and safety (approximately 280 patients in each) and a third evaluating safety only (approximately 480 patients). Enrollment in these three Phase 3 trials is complete. Two of the trials, each evaluating efficacy and safety of OMS103HP, were conducted in patients receiving grafts from cadavers or their own tissue, respectively. The safety only trial included patients receiving either graft type. Efficacy endpoints include assessments of postoperative knee function and range of motion, pain reduction and return to work. We expect to release the results from this program during the first quarter of 2011.

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The second program is evaluating OMS103HP's safety and ability to improve postoperative joint function and reduce pain following arthroscopic meniscectomy surgery. We are finalizing preparations to begin enrollment in a Phase 3 clinical study of OMS103HP in patients undergoing partial meniscectomy surgery and will decide whether and when to begin enrollment in this study after we review the data from our Phase 3 ACL program.

### *OMS302 Ophthalmology*

*Background.* OMS302 is our PharmacoSurgery product candidate being developed for use during ophthalmological procedures including cataract and other lens replacement surgery. OMS302 is a proprietary combination of an anti-inflammatory API and an API that causes pupil dilation, or mydriasis, each with well-known safety and pharmacologic profiles. 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. Added to standard irrigation solution used in cataract and other lens replacement surgery, OMS302 is being developed for delivery into the anterior chamber of the eye, or intracameral delivery, to maintain mydriasis, to prevent surgically induced pupil constriction, or miosis, and to reduce postoperative pain and irritation. Mydriasis is an essential prerequisite 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.* We conducted a Phase 1/Phase 2 clinical trial evaluating the efficacy and safety of OMS302 added to standard irrigation solution and delivered to patients undergoing cataract surgery. The purpose of the study was to demonstrate the proof of concept that a surgical irrigation solution containing a mydriatic API improves maintenance of mydriasis during cataract surgery and that a surgical irrigation solution containing an anti-inflammatory API improves pain control and lessens inflammation following surgery. In this study, 61 patients were randomized to receive one of three treatments: (1) OMS302, (2) the mydriatic API of OMS302 alone, or OMS302-mydriatic, and (3) vehicle control. For efficacy assessments, patients were monitored for pupil size during surgery and pain and inflammation for 14 days following the surgery.

Patients treated with OMS302 reported less postoperative pain than patients treated with either OMS302-mydriatic or vehicle control. Patients treated with either OMS302 or OMS302-mydriatic demonstrated statistically significant improvement in maintenance of mydriasis compared to patients treated with 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 three treatment groups. Three of the total 61 patients (two in the OMS302 group and one in the OMS302-mydriatic group) reported mild to moderate eye pain judged by the investigator to be either possibly or probably treatment-related.

Overall, this study suggests that OMS302 would be useful in helping maintain mydriasis during surgery and controlling pain immediately following surgery.

*Development Plan.* We are conducting a Phase 2b clinical trial for OMS302 to assess the effect of a fixed concentration of the mydriatic API alone and in combination with the anti-inflammatory API in a full-factorial design. Enrollment for this study is complete and we expect to announce data from this Phase 2b trial in the first quarter of 2011. Approximately 200 patients were enrolled in the multicenter, randomized, double-blind, vehicle-controlled Phase 2b clinical trial. Patients were randomized into one of four parallel treatment groups of equal size. The first arm received OMS302, the second and third received only the mydriatic agent or the anti-inflammatory agent, respectively, and the fourth arm received a placebo of standard irrigation solution without drug. The co-primary endpoints of the study include the reduction of post-operative ocular pain and maintenance of mydriasis (pupil dilation).

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### *OMS201 Urology*

*Background.* OMS201 is our PharmacoSurgery product candidate 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.* We completed a Phase 1/Phase 2 study 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, placebo-controlled study also explored potential efficacy endpoints but was not powered to assess efficacy. OMS201 was safe and 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.* Based on the data from our recently completed Phase 1/Phase 2 clinical study, we are designing subsequent trials to evaluate the efficacy and safety of OMS201 in patients undergoing urologic procedures.

### **PPAR $\gamma$ Program**

*Overview.* In our peroxisome proliferator-activated receptor gamma, or PPAR $\gamma$ , program, we are developing proprietary compositions that include PPAR $\gamma$  agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine and alcohol. We believe that Omeros is the first to demonstrate a link between PPAR $\gamma$  and addiction disorders. Data from European pilot clinical studies and animal models of addiction suggest that PPAR $\gamma$  agonists could be efficacious in the treatment of a wide range of addictions. Our collaborators at The New York State Psychiatric Institute are conducting two Phase 2 clinical trials for our PPAR $\gamma$  program. These studies are evaluating a PPAR $\gamma$  agonist, alone or in combination with other agents, for the abuse liability potential of oxycontin and for the treatment of addiction to heroin. 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 PPAR $\gamma$  program.

*Patent Assignment Agreement with Roberto Ciccocioppo, Ph.D.* We acquired the patent applications and related intellectual property rights for our PPAR $\gamma$  program in February 2009 from Roberto Ciccocioppo, Ph.D. of the Università di Camerino, Italy, pursuant to a Patent Assignment Agreement. In February 2010, we amended the agreement to include all intellectual property rights, including patent applications, related to nutraceuticals that increase PPAR $\gamma$  activity. Under the amended agreement, we have agreed to pay Dr. Ciccocioppo a low-single digit percentage royalty on net sales of any products that are covered by any patents that issue from the patent applications that we acquired from him. In addition, if we grant any third parties rights to manufacture, sell or distribute any such products, we must pay to Dr. Ciccocioppo a percentage of any associated fees we

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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.

### **GPCR Program**

*Overview.* G protein-coupled receptors, or GPCRs, comprise one of the largest families of proteins in the genomes of multicellular organisms. According to Insight Pharma Reports, or IPR, 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. According to IPR, 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, or orphan GPCRs. Without a known ligand, there is no template from which medicinal chemistry efforts can be readily initiated nor a means to identify the GPCR's signaling pathway and, therefore, drugs cannot easily be developed against orphan GPCRs. Unlocking these orphan GPCRs could lead to the development of drugs that act at these new targets. To our knowledge, despite efforts by others in the biopharmaceutical industry, Omeros' technology is the first commercially viable technology capable of identifying ligands of orphan GPCRs in high throughput.

We have scientific expertise in the field of GPCRs and members of our scientific team were the first to identify and characterize all GPCRs common to mice and humans, with the exception of sensory GPCRs. Our work was published in a peer-reviewed article titled "The G protein-coupled receptor repertoires of human and mouse" that appeared in the April 2003 issue of *Proceedings of the National Academy of Sciences* (Vol. 100, No. 8: pp. 4903-4908). In addition, our proprietary cellular redistribution assay, or CRA, can be used in a high-throughput manner to identify synthetic ligands, including antagonists, agonists and inverse agonists, that bind to and affect the function of orphan GPCRs. We also have developed a proprietary rapid mouse gene knock-out platform technology, which is described in a peer-reviewed article titled "Large-scale, saturating insertional mutagenesis of the mouse genome" that appeared in the September 2007 issue of *Proceedings of the National Academy of Sciences* (Vol. 104, No. 36: pp. 14406-14411). We have used this platform to create 61 different GPCR-specific strains of knock-out mice, and we have established a battery of behavioral tests that allows us to characterize these knock-out mice and identify candidate drug targets. The genes disrupted in these strains of knock-out mice include those linked to orphan GPCRs. In addition, we have developed a platform technology to

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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 orphan GPCRs against our small-molecule chemical libraries using the CRA. Based on the limited screening of libraries to date, we have already announced that we have identified and confirmed sets of compounds that interact selectively with, and modulate signaling of a series of orphan GPCRs, including orphans linked to squamous cell carcinoma (GPR87), pancreatic cancer (GPR182), obesity (GPR85), appetite control (GPR101) and cognitive disorders (GPR12).

*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 that will be used to reimburse us for expenses that we incur and equipment we purchase 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 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. After we have received approximately \$1.5 billion of cumulative net proceeds, 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 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.

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 warrants may be exercised for cash or on a "cashless" basis through the surrender at the time of exercise of a number of shares that would otherwise be issuable equal to the fair market value of our common stock at the time of exercise. 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 CAD. We completed the acquisition of these assets on November 22, 2010 by paying to Patobios \$7.8 million CAD (\$7.6 million USD) in cash and the remaining \$3.0 million CAD (\$3.2 million USD) in the form of 379,039 shares of our common stock.

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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 shall be junior to any existing or future security interests granted in connection with a financing transaction and which shall 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. If for any reason LSDF does not provide the full \$5.0 million to us, LSDF's percentage share of net proceeds will be reduced in proportion to the amount it actually pays to us. 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.

In addition, pursuant to our agreements with Vulcan and LSDF, we have agreed (1) to use commercially reasonable efforts to screen at least 75% of the currently known human Class A orphan GPCRs within 19 months of October 21, 2010, subject to possible extensions and (2) to commence a medicinal chemistry effort focused on developing a product candidate with respect to one orphan GPCR for which compounds were identified using the GPCR assay technology.

## **Preclinical Programs**

### ***Plasmin Program***

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

Prior to withdrawal from the market 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 are derived from tissue factor pathway inhibitor-2, or TFPI-2. A single domain of TFPI-2, referred to as KD1, inhibits plasmin but, like Trasylol®, also inhibits kallikrein and Factor XIa. Researchers demonstrated that a minimal change to the sequence of the KD1 protein increases its activity against plasmin approximately 6-fold, while dramatically reducing its inhibition of kallikrein and Factor XIa by more than 100-fold. This work appears 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*. Because the variant KD1 proteins developed by the authors and exclusively licensed to Omeros are more selective than Trasylol®,

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they could provide more effective bleeding control with fewer side effects. Additionally, as a human protein derivative, these agents are expected to reduce the potential for immunological side effects. We believe the efficacy and improved selectivity of the variant KD1 provides 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.

### ***PDE7 Program***

*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 and currently are conducting additional studies evaluating the effects of potential clinical candidates in models of addiction and compulsive disorders as well as Parkinson's disease. Our collaborators on this program include the National Institute on Drug Abuse and The Michael J. Fox Foundation.

*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 movement disorders and other specified indications, or Indication 1, as well as for use in the treatment of addiction and compulsive disorders, or Indication 2. Under the agreement, we agreed to make milestone payments to Daiichi Sankyo of up to an aggregate total of \$30.2 million upon the achievement of certain events related to Indication 1 and Indication 2; however, if only one of the two 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.

### ***MASP-2 Program***

*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

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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. 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.

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 wet age-related macular degeneration, ischemia-reperfusion injury, transplant-related complications and radiation injury. We are continuing to evaluate the role of MASP-2 in 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, and from Helion Biotech ApS.

*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 the Medical Research Council at Oxford University, or 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 Biotech ApS, or 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 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 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.

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### ***PDE10 Program***

*Overview.* Phosphodiesterase 10, or PDE10, is an enzyme that is expressed in areas of the brain strongly linked to schizophrenia and other psychotic disorders and has been recently identified as a target for the development of anti-psychotic therapeutics. We are developing proprietary compounds that inhibit PDE10 for the treatment of schizophrenia and other psychotic disorders. 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.

*Funding Agreement with The Stanley Medical Research Institute.* Our preclinical development is 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 may receive grant and equity funding upon achievement of product development milestones through Phase I clinical trials totaling \$9.0 million, subject to our mutual agreement with SMRI. Through December 31, 2010, we have received \$5.7 million from SMRI, \$3.2 million of which was recorded as equity funding, \$2.3 million was recorded as revenue and \$227,000 remains in deferred 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 have received as of December 31, 2010, 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.

### **Sales and Marketing**

We have retained all marketing and distribution rights to our product candidates and programs, which provides us the opportunity to market and sell any of our product candidates independently, make arrangements with third parties to perform these services for us, or both. For the commercial launch of our lead product candidate, OMS103HP, we intend to use a combination of orthopedic specialty distributors and our own internal sales and marketing organization to market OMS103HP in North America and, for markets outside of North America, we intend to utilize similar distribution networks or work with third parties to perform these services. Because OMS103HP, if approved, will be used principally by surgeons in hospital-based and freestanding ambulatory surgery centers, we believe that commercializing OMS103HP will only require a limited sales and marketing force.

We expect that an OMS103HP sales and marketing force is potentially scalable for both of our other PharmacoSurgery product candidates, OMS302 and OMS201. For the sales and marketing of other product candidates, we generally expect to retain marketing and distribution rights in those for which we believe that it will be possible to access markets through an internal sales and marketing force. If we do not believe that we can cost-effectively access markets for any approved product candidate through an internal sales and marketing force, we expect that we will make arrangements with third parties to perform these 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 product candidates, which need not be manufactured in compliance with current Good Manufacturing Practices, or cGMPs. We utilize outside contract manufacturers to produce sufficient quantities of product candidates for use in preclinical studies.

We rely on third-party manufacturers to produce, store and distribute our product candidates for clinical use and currently do not own or operate manufacturing facilities. We require that these manufacturers produce active pharmaceutical ingredients, or APIs, and finished drug products in accordance with cGMPs and all other applicable

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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 product candidates.

We contracted with Catalent Pharma Solutions, Inc. to manufacture three batches of OMS103HP in freeze-dried, or lyophilized, form. Ongoing stability programs for these batches will be used to support the planned filing of a New Drug Application, or NDA, for OMS103HP. Pursuant to our stability study agreements with Catalent, we have agreed to pay Catalent for its performance of stability studies of three lots of lyophilized OMS103HP in accordance with cGMPs. These agreements terminate upon completion of the stability studies, provided that we may terminate these agreements at any time upon notice to Catalent. We have received guidance from the FDA that submission of three months of stability data from one registration batch of lyophilized OMS103HP would be sufficient to qualify any other facility for commercial manufacturing purposes.

We have also formulated OMS103HP as a liquid solution to take advantage of the reduced cost of goods for manufacturing a liquid as compared to a lyophilized drug product and, if approved for marketing, intend to launch OMS103HP as a liquid solution. Although we do not believe that the inactive ingredients in liquid OMS103HP, which are included in the FDA's Inactive Ingredient Guide due to being present in drug products previously approved for parenteral use, impact its safety or effectiveness, the FDA will require us to provide comparative information and complete a stability study in connection with a potential NDA submission. We completed a nonclinical study that demonstrated that liquid OMS103HP is as safe as lyophilized OMS103HP; however, the FDA may require us to conduct additional studies. We have entered into agreements with Hospira Worldwide, Inc., 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 ninety 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 three suppliers for the three APIs used in our clinical supplies of OMS103HP. We have not yet signed commercial agreements with any suppliers for the supply of commercial quantities of these APIs,

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although we intend to do so prior to the commercial launch of OMS103HP. 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 OMS103HP.

We have undertaken the development of MASP-2 antibodies with two independent antibody developers, Affitech AS and North Coast Biologics, LLC. In March 2010 we amended our antibody development agreement with Affitech. Under the terms of the amendment, Affitech has released us from any future obligations to make royalty or milestone payments in exchange for \$500,000. Our antibody development agreement with North Coast requires us to pay a low single-digit percentage royalty on net sales of any product containing an antibody developed for us by North Coast and milestone payments of up to \$4.0 million. The milestone payments are payable upon the occurrence of certain development events, such as the delivery of a product candidate meeting certain criteria, initiation of clinical trials and receipt of marketing approval. The terms of these agreements continue until all of the services called for in the applicable agreement have been provided by the antibody developer and there are no pending patent applications or valid and enforceable claims included with any patent related to MASP-2 antibodies developed by such developer under the agreement, except that our agreement with North Coast may not terminate earlier than October 31, 2020. These agreements may be terminated prior to the end of their terms upon the occurrence of certain events such as breach of contract. We have the right under these agreements to require these developers to transfer the materials they create for us to third parties for further development and manufacturing of MASP-2 antibodies. In addition, under our North Coast antibody development agreement, North Coast has agreed to develop additional antibodies for us against targets that we select on or before October 31, 2020. If we do select additional targets, we may have to pay North Coast a technology access fee and we will have royalty and milestone payment obligations of up to \$4.1 million per target for any related antibodies that are similar to our obligations for any MASP-2 antibody developed by North Coast. We intend to enter into an agreement with a third-party contract manufacturer for the scale-up and production of a MASP-2 monoclonal antibody product candidate for clinical testing and potentially commercial supply.

## **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 product candidates, or that reach the market before our approved product candidates, we may not achieve commercial success. We are not aware of any products that directly compete with our PharmacoSurgery product candidates that are approved for intra-operative delivery in irrigation solutions during surgical procedures; however, our PharmacoSurgery product candidates could compete with preoperative and postoperative treatments for pain and inflammation. If approved, we expect that the primary constraint to market acceptance of our PharmacoSurgery product candidates will be surgeons who continue with their respective current treatment practices and do not adopt the use of these product candidates as well as the level of reimbursement surgeons receive for the administration of our product candidates.

Our other clinical and preclinical product candidates may face competing products. For example, we are developing PDE10 inhibitors for use in the treatment of schizophrenia and other psychotic disorders. Other pharmaceutical companies, many with significantly greater resources than us, are also developing PDE10 inhibitors for the treatment of schizophrenia and other psychotic disorders and these companies may be further along in development. In addition, we believe 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 any products developed from our product candidates;

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operate larger research and development programs, possess greater manufacturing capabilities or have substantially greater financial resources than we do;

initiate or withstand substantial price competition more successfully than we can;

have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;

more effectively negotiate third-party licenses and strategic relationships; and

take advantage of acquisition or other opportunities more readily than we can.

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

## **Intellectual Property**

As of March 7, 2011, we owned a total of 27 issued or allowed patents and 37 pending patent applications in the United States and 112 issued or allowed patents and 122 pending patent applications in foreign markets directed to therapeutic compositions and methods related to our PharmacoSurgery platform, GPCR program and preclinical development programs. As of March 7, 2011, we also held worldwide exclusive licenses to five issued or allowed patents and two pending patent applications, in the United States and 17 issued or allowed patents and 18 pending patent applications in foreign markets. 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 intra-operatively to the site of any medical or surgical procedure. As of March 7, 2011, our patent portfolio included 14 U.S. and 24 foreign issued or allowed patents, and seven U.S. and 24 foreign pending patent applications, directed to our PharmacoSurgery product candidates and development programs. Our issued PharmacoSurgery patents have terms that will expire December 12, 2014 and, assuming issuance of currently pending patent applications, October 20, 2019 for OMS103HP, July 30, 2023 for OMS302 and March 17, 2026 for OMS201. We intend to file additional patent applications directed to our specific drug products which, if issued, are expected to provide patent terms ending 2031 or later.

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

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preferred for use in arthroscopic procedures, ophthalmologic procedures including intraocular procedures, and urologic procedures including ureteroscopy, for OMS103HP, OMS302 and OMS201, respectively, as well as covering the specific combinations of agents included in each of these product candidates.

*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 March 7, 2011, we owned four issued U.S. Patents, two pending U.S. Patent Applications, and 33 issued patents and 5 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, Hong Kong, Japan, Mexico, Norway, Russia, Singapore and South Korea) that cover OMS103HP.

*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 March 7, 2011, we owned one pending U.S. Patent Applications and 11 issued patents and 9 pending patent applications in foreign markets (Australia, Canada, China, Europe, Hong Kong and Japan) that cover OMS302.

*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 March 7, 2011, we owned three issued U.S. Patents, two pending U.S. Patent Applications, and an additional 22 issued patents and 15 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.

*PPARg Program.* As of March 7, 2011, we owned two pending U.S. Patent Applications and 13 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, India, Japan, Mexico, New Zealand, Russia, South Korea and International Patent Cooperation Treaty) directed to the recently discovered link between PPARg and addictive disorders.

*GPCR Program.* As of March 7, 2011, we owned three issued patents and four pending patent applications in the United States, and 41 issued patents and ten 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.

*Plasmin Program.* We hold worldwide exclusive licenses to a series of antifibrinolytic agents from The Regents of the University of California. As of March 7, 2011, we exclusively controlled one issued patent and one pending patent application in the United States and four pending patent applications in foreign markets (Australia, Canada, Europe and Japan) that are directed to these proprietary agents.

*PDE7 Program.* As of March 7, 2011, we owned two pending U.S. Patent Applications and 12 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 two pending U.S. Patent Applications directed to the link between PDE7 and addiction and compulsive disorders. Additionally, under a license from Daiichi Sankyo Co., Ltd. we exclusively control rights to two issued U.S. Patents and ten issued and 13 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.



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*MASP-2 Program.* 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 Biotech ApS. As of March 7, 2011, we exclusively controlled four issued patents and nine pending patent applications in the United States, and nine issued patents and 38 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Hong Kong, Europe, India, Indonesia, Japan, Mexico, New Zealand, Russia and South Korea) related to our MASP-2 program.

*PDE10 Program.* As of March 7, 2011, we own one issued patent and four pending patent applications in the United States, and eight pending patent applications in foreign markets (Australia, Canada, China, Europe, India, Japan and New Zealand) that claim proprietary PDE10 inhibitors.

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 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 product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the 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 product candidates and programs. Some of our product candidates 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.

*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 Our Product Candidates and Development Programs PPARg Program.

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*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 August 2006. 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 CAD.

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

*PDE7 and PDE10 Programs.* We acquired our PDE7 and PDE10 programs and some of our related patents and other intellectual property rights as a result of our acquisition of nura, inc. in August 2006. We hold an exclusive license to certain PDE7 inhibitors claimed in patents and pending patent applications owned by Daiichi Sankyo Co., Ltd. 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 Our Product Candidates and Development Programs PDE7 Program.

*MASP-2 Program.* We hold worldwide exclusive licenses to rights related to MASP-2, the antibodies targeting MASP-2 and the therapeutic applications for the antibodies from the University of Leicester, Medical Research Council at Oxford University, or MRC, and Helion Biotech ApS, or Helion. For more detailed descriptions of these licenses, see Business Our Product Candidates and Development Programs MASP-2 Program.

## **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 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 a delay in approving or refusal to approve pending applications, warning letters, product recalls, product seizures, 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 under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and implementing regulations. Before our drug products may be marketed in the United States, each must be approved by the FDA. Our product candidates are in various stages of testing and none have been approved.

The steps required before a drug 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 Investigational New Drug Application, or 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 candidate for each indication for which approval is sought;

submission to the FDA of a New Drug Application, or NDA;

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

FDA review and approval of an NDA.

*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 candidate. The results of the preclinical tests, together with manufacturing information, analytical data, and other available information are submitted to the FDA as part of an IND.

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*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, 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 drug 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:

Phase 1 usually involves the initial administration of the investigational drug product to human subjects to evaluate its safety, dosage tolerance, pharmacodynamics and, if possible, to gain an early indication of its effectiveness.

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

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

We, our product development partners, 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 NDA 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 requesting approval to market the product for one or more indications. Before approving an NDA, 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 NDA is not acceptable, the FDA may outline the deficiencies in the NDA 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 new NDA or, in some instances, an NDA supplement, for further FDA review and approval. Post-approval marketing of products in larger patient populations than 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.

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The FDA regulates certain of our candidate products as combination drugs under its Combination Drug Policy 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.

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 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 problems may result in changes in labeling or restrictions on a product manufacturer or NDA 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 vary widely 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 \$23.5 million, \$16.9 million and \$17.9 million in 2010, 2009 and 2008, respectively.

## **Employees**

As of February 28, 2011, we had 70 full-time employees, 55 of whom are in research and development and 15 of whom are in finance, legal, business development and administration, including three 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 February 28, 2011:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
<i>Executive Officers:</i>		
Gregory A. Demopoulos, M.D.	52	President, Chief Executive Officer and Chairman of the Board of Directors
Marcia S. Kelbon, J.D.	51	Vice President, Patent and General Counsel and Secretary
<i>Key Employees:</i>		
Timothy M. Duffy	50	Vice President, Business Development
Kenneth M. Ferguson, Ph.D.	55	Vice President, Development
George A. Gaitanaris, M.D., Ph.D.	54	Vice President, Science
Wayne R. Gombotz, Ph.D.	51	Vice President, Pharmaceutical Operations
J. Greg Perkins, Ph.D.	66	Vice President, Regulatory Affairs and Quality Systems
David R. Toll	43	Senior Director of Finance
J. Steven Whitaker, M.D., J.D.	55	Vice President, Clinical Development and Chief Medical Officer

*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.* 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 Nantech 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. From August 2008 to November 2010, Dr. Ferguson served in various positions, including president, chief executive officer and executive director as well as a consultant, for VacTX International Inc., a biotechnology company. From 1990 to 2007, Dr. Ferguson served at ICOS Corporation. Prior to its acquisition in 2007 by Eli Lilly and Company, Dr. Ferguson served at ICOS as vice president, therapeutic development. He also served as chief operating officer, chief scientific officer and a member of the board of managers of Lilly ICOS LLC, the joint

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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. 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 in New York and his M.D. from the Aristotelian University of Greece.

*Wayne R. Gombotz, Ph.D.* has served as our vice president, pharmaceutical operations since March 2005. From 2002 to 2005, Dr. Gombotz served as vice president, process science and pharmaceutical development at Corixa Corporation, a company that developed immunotherapeutic products and which was acquired by GlaxoSmithKline plc in July 2005. From 1995 to 2002, Dr. Gombotz served as senior director, analytical chemistry and formulation at Immunex Corporation, a company that developed immunotherapeutic products and was acquired by Amgen, Inc. in July 2002. Dr. Gombotz received his Ph.D. and M.S. in bioengineering from the University of Washington and his B.A. from Colby College.

*J. Greg Perkins, Ph.D.* has served as our vice president, regulatory affairs and quality systems since April 2006. From 2004 to 2005, Dr. Perkins served as president of Bioderm Sciences, Inc., a company engaged in the development of wound management, first aid and sports medicine products. From 1994 to 2004, Dr. Perkins served in various positions at Solvay Pharmaceuticals, Inc., a pharmaceutical company, most recently as senior vice president, global scientific affairs and milestone review. Dr. Perkins received his Ph.D. in biochemistry and B.S. from Indiana University and completed a postdoctoral fellowship in neurochemistry at the University of Iowa.

*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, 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 investment and development company. From May 1994 to May 2007, Dr. Whitaker served at ICOS Corporation, which was acquired by Eli Lilly & 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.

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### **Corporate Information**

We were incorporated as a Washington corporation on June 16, 1994. Our principal executive offices are located at 1420 Fifth Avenue, Suite 2600, Seattle, Washington, 98101, and our telephone number is (206) 676-5000. Our web site address is [www.omeross.com](http://www.omeross.com). We make available, free of charge through our 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 Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the 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).

### **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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, 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, and potential, and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding:

our ability to release the results from our Phase 3 clinical program of OMS103HP during the first quarter of 2011;

our ability to market OMS103HP by 2012, at the earliest;

our ability to release the results from our Phase 2b clinical trial of OMS302 during the first quarter of 2011;

our expectations regarding the clinical benefits of our product candidates, including whether OMS103HP will be the first commercially available drug delivered directly to the surgical site to improve function following arthroscopic surgery;

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

our expectations regarding the growth in the number of arthroscopic operations, the rate at which OMS103HP will be reimbursed to the surgical facility for its utilization and to the surgeon for its use, the size of the markets for OMS103HP and the rate and degree of adoption and market penetration of OMS103HP;

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 product candidates, our competition and, if approved, our ability to successfully commercialize our PharmacoSurgery product candidates with a limited, hospital-based marketing and sales force;

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our expectation that an OMS103HP sales and marketing force is scalable for both of our other PharmacoSurgery product candidates, OMS302 and OMS201;

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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 expectation that we will be able to borrow an additional \$10.0 million from Oxford Finance Corporation pursuant to our existing loan facility;

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 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 this Annual Report on Form 10-K under the heading "Risk Factors" and in our other filings with the Securities and Exchange Commission. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, 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.

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**ITEM 1A. RISK FACTORS**

*Our business, prospects, financial condition or operating results could be materially adversely affected by any of the risks described below, as well as other risks not currently known to us or 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 Product Candidates, Programs and Operations**

**Our success largely depends on the success of our lead PharmacoSurgery product candidate, OMS103HP, and we cannot be certain that it will receive regulatory approval or be successfully commercialized. If we are unable to commercialize OMS103HP, or experience significant delays in doing so, our business will be materially harmed.**

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 will continue to incur, significant costs relating to the development and commercialization of our lead product candidate, OMS103HP, for use during arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery as well as arthroscopic partial meniscectomy surgery. We have not yet obtained regulatory approval to market this product candidate for ACL reconstruction surgery, arthroscopic partial meniscectomy surgery or any other indication in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize this product candidate successfully. There can be no assurance that the data will be positive from any of our clinical trials of OMS103HP, including our Phase 3 clinical program evaluating OMS103HP in ACL reconstruction surgery. We expect to announce date from this Phase 3 study in the first quarter of 2011. If the data are not positive, our business and prospects could be harmed materially and the trading price of our stock could decline significantly. Even if the data are positive, the FDA may decide that our clinical studies or data are insufficient for approval of OMS103HP and require additional preclinical, clinical or other studies. If OMS103HP does not receive regulatory approval for ACL reconstruction surgery or arthroscopic partial meniscectomy surgery or if approval is delayed beyond our current expectations, or if it is not successfully commercialized for one or both uses, we may not be able to generate revenue, become profitable, fund the development of our other product candidates or preclinical development programs or continue our operations.

We do not know whether our clinical trials for OMS103HP will be completed on schedule or result in regulatory approval or in a marketable product. If approved for commercialization, we do not anticipate that OMS103HP will reach the market until 2012 at the earliest.

**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 product candidates, we, our product candidates, 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; fines and other monetary penalties; unanticipated expenditures; delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating restrictions; injunctions; and criminal prosecution. We or the U.S. Food and Drug Administration, or FDA, or an institutional review board, or IRB, 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.

Our product candidates cannot be marketed in the United States without FDA approval, and can only be marketed for the indications, if any, for which they may be approved. The FDA has not approved any of our

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product candidates for sale in the United States. All of our product candidates 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 product candidates and require additional preclinical, clinical or other studies. As we develop our product candidates, we periodically discuss with the FDA clinical, regulatory and manufacturing matters, and our views may, at times, differ from those of the FDA. For example, the FDA has questioned whether our studies evaluating OMS103HP in patients undergoing ACL reconstruction surgery are adequately designed to evaluate efficacy. If these studies fail to demonstrate efficacy, we will be required to provide additional information, including possibly the results of additional clinical trials. Also, the FDA regulates those of our product candidates consisting 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 product candidates 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 product candidates, or may never be able to obtain marketing approval.

Even if regulatory approval of a product candidate is obtained, such approval may be subject to significant limitations on the indicated uses for which that product may be marketed, conditions of use, and/or significant post approval obligations, including additional 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 success is also dependent on the success of our additional PharmacoSurgery product candidates, OMS302 and OMS201, and we cannot be certain that either will advance through clinical testing, receive regulatory approval or be successfully commercialized.**

In addition to OMS103HP, our success will depend on the successful commercialization of one or both of two additional PharmacoSurgery product candidates, OMS302 and OMS201. We have incurred and will continue to incur significant costs relating to the clinical development and commercialization of these PharmacoSurgery product candidates. We have not obtained regulatory approval to market these product candidates for any indication in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize these product candidates successfully. If OMS302 and OMS201 do not receive regulatory approval, or if they are not successfully commercialized, we may not be able to generate revenue, become profitable, fund the development of our other product candidates or our preclinical programs or continue our operations.

We do not know whether our planned and current clinical trials for OMS302 and OMS201 will be completed on schedule, if at all. In addition, we do not know whether any of our clinical trials will be successful or result in approval of either product for marketing.

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### **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 \$29.3 million and \$21.1 million for the twelve months ended December 31, 2010 and 2009, respectively. As of December 31, 2010, we had an accumulated deficit of approximately \$147.6 million. We 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 product candidates, to develop a market for our potential products, to successfully transition from a company with a research and development focus to a company capable of commercializing our product candidates and to attract and retain qualified management as well as technical and scientific staff.

### **If our clinical trials are delayed, we may be unable to develop our product candidates on a timely basis, which will increase our development costs and delay the potential commercialization of our 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, IRBs 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 IRBs or other governing 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 or unacceptable design;

an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;

the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval;

an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation;

the occurrence of drug-related side effects or adverse events experienced by participants in our clinical trials; or

the placement of a clinical hold on a trial.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

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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, or CROs, and other third parties.

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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 IRBs for reexamination, 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 approval process, would delay our receipt of product revenue and would make it difficult to raise additional capital. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products and may harm our business.

### **If we are unable to raise additional capital when needed or on acceptable terms, we may be unable to complete the development and commercialization of OMS103HP and our other product candidates, 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:

begin commercialization activities for OMS103HP for use in arthroscopic ACL reconstruction surgery, assuming that we receive positive data from our ongoing Phase 3 clinical program;

initiate, conduct and complete the Phase 3 clinical trials of OMS103HP for use in arthroscopic partial meniscectomy surgery, should we elect to proceed with these Phase 3 clinical trials;

conduct and complete the clinical trials of OMS302 for use during lens replacement surgery;

conduct and complete the clinical trials of OMS201 for use in endoscopic surgery of the urological tract;

purchase the equipment and research tools and pay all of the related research and development costs necessary to screen orphan GPCRs and commence related medicinal chemistry efforts as required pursuant to our GPCR program funding agreements with Vulcan and LSDF;

scale-up and produce clinical supplies of product candidates, including for our Plasmin and MASP-2 programs;

continue research and development in all of our programs;

make milestone payments to our collaborators;

make principal and interest payments when due under our debt facility with Oxford Finance Corporation, or Oxford;

initiate and conduct clinical trials for other product candidates; and

launch and commercialize any product candidates for which we receive regulatory approval.

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Our clinical trials for OMS103HP may be delayed or we may need to conduct additional trials for many of the reasons discussed in these Risk Factors, which would increase the development expenses of OMS103HP and may require us to raise additional capital to complete the clinical development and commercialization of OMS103HP and to decrease spending on our other clinical and preclinical development programs.

**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.**

In October 2010 we borrowed \$10.0 million pursuant to the terms of a loan and security agreement with Oxford. In addition, at any time before March 31, 2011 we may, at our sole option, borrow from Oxford an

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additional \$10.0 million, subject to our satisfaction of specified conditions precedent described in the loan agreement. As collateral for these loans, 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 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 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.

### **Our lead product candidate OMS103HP or future product candidates may never achieve market acceptance even if we obtain regulatory approvals.**

Even if we receive regulatory approvals for the commercial sale of our lead product candidate OMS103HP or future product candidates, the commercial success of these product candidates will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community. If our product candidates 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 candidate 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 surgical procedure or condition for which the product is approved;

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 prevalence and severity of adverse side effects;

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publicity concerning our products or competing products and treatments; and

our ability to obtain sufficient third-party reimbursement for our products.

The number of operations in which our PharmacoSurgery products, if approved, would be used may be significantly less than the total number of operations performed according to the market data obtained from industry sources. If our lead product candidate OMS103HP or future product candidates 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 OMS103HP or our other product candidates, our growth will be significantly harmed.

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**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, we may not be able to obtain regulatory approval for or commercialize our product candidates.**

We rely on third parties, such as CROs and research institutions, to conduct a portion of our preclinical research. We also rely on third parties, such as medical institutions, clinical investigators and CROs, to assist us in conducting our clinical trials. Nonetheless, we are responsible for confirming that our preclinical research is conducted in accordance with applicable regulations, and that our clinical trials are conducted in accordance with applicable regulations, the relevant protocol and within the context of approvals by an IRB. Our reliance on these third parties does not relieve us of responsibility for ensuring compliance with FDA 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 product candidates.

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

We do not have a sales and marketing organization and 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 product candidates that we develop ourselves. Factors that may inhibit our efforts to commercialize our approved product candidates without collaboration partners include:

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

the inability of sales personnel to obtain access to or persuade adequate numbers of hospitals, surgery centers, physicians and/or pharmacists to purchase, use or prescribe our approved product candidates;

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 product candidates, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

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

We do not intend to manufacture our product candidates for our clinical trials or on a commercial scale and intend to rely on third parties to do so. Our clinical supplies of OMS103HP were manufactured in a freeze-dried, or lyophilized, form by Catalent Pharma Solutions, Inc. in its Albuquerque, New Mexico facility. In May 2008, Catalent announced that it sold this facility to OSO Biopharmaceuticals Manufacturing, LLC, or OSO, which continues to manufacture lyophilized drug products at this facility. We have not entered into a binding agreement with Catalent or OSO for the commercial supply of lyophilized OMS103HP, and cannot be certain that we would be able to do so on commercially reasonable terms. Qualification of any other facility to manufacture lyophilized



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OMS103HP would require transfer of manufacturing methods, the production of one or more additional registration batches of lyophilized OMS103HP and the generation of additional stability data, which could delay the availability of commercial supplies of lyophilized OMS103HP.

We have also formulated OMS103HP as a liquid solution and, if approved for marketing, intend to launch OMS103HP as a liquid solution. We have entered into an agreement with Hospira Worldwide, Inc. for the commercial supply of liquid OMS103HP. We do not believe that the inactive ingredients in liquid OMS103HP, which are included in the FDA's Inactive Ingredient Guide due to being present in drug products previously approved for parenteral use, impact its safety or effectiveness. The FDA will require us to provide comparative information and complete a stability study in connection with a potential NDA submission. We have completed a nonclinical study that demonstrates that liquid OMS103HP is as safe as lyophilized OMS103HP; however, the FDA may require us to conduct additional studies. Delays, unexpected results in these studies or any requirement to conduct additional studies could delay the commercial availability of liquid OMS103HP. Any significant delays in the manufacture of clinical or commercial supplies could materially harm our business and prospects.

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

Contract manufacturers that we select to manufacture our product candidates 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 product candidates. Once a product candidate 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, or cGMP, 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 cGMP requirements or with other FDA, state, local and foreign regulatory requirements. We have little control over our contract manufacturers' compliance with these regulations and standards or with their quality control and quality assurance procedures but we are responsible for their compliance. Large-scale manufacturing processes have been developed only for lyophilized OMS103HP. For the liquid formulation of OMS103HP and our other product candidates, development of large-scale manufacturing processes will require validation studies, which the FDA must review and approve. Failure to comply with these requirements by our contract manufacturers could result in the issuance of untitled letters and/or warning letters from 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 candidate supplied by contract manufacturers is compromised due to their failure to adhere to applicable laws or for other reasons, we may not be able to obtain or maintain regulatory approval for or successfully commercialize one or more of our product candidates, which would harm our business and prospects significantly.

If one or more of our contract manufacturers were to encounter any of these difficulties or otherwise fail to comply with its contractual obligations, our ability to provide product candidates to patients in our clinical trials or on a commercial scale would be jeopardized. Any delay or interruption in the supply of clinical trial 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

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and comparable foreign regulators must first approve these manufacturers' facilities and processes, which would 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 product candidates.

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

We must purchase from third-party suppliers the ingredients necessary for our contract manufacturers to produce our PharmacoSurgery product candidates 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 product candidates, 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 manufacturer for our clinical trials, potential regulatory approval of our product candidates would be delayed, significantly impacting our ability to develop our product candidates, which would materially affect our ability to generate revenue from the sale of our product candidates.

**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 product candidates that are proprietary to one or more third parties, we would need to obtain licenses to those active ingredients from those third parties. For example, we intend to use proprietary active ingredients that we have exclusively licensed from Daiichi Sankyo Co., Ltd. for our PDE7 program and we may use proprietary active ingredients in some of our future GPCR product candidates. We do not have licenses to any of the proprietary active ingredients we may elect to use in these potential future GPCR product candidates. If we are unable to access rights to these active ingredients prior to preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, we may not be able to commercialize product candidates from these programs.

**Our agreements with Vulcan and LSDF contain covenants that may limit our ability to redirect research and development efforts away from our GPCR program to other programs that may be more profitable or for which there is a greater likelihood of success.**

On October 21, 2010, we received \$20.0 million from an affiliate of Vulcan Inc., which we refer to collectively as Vulcan, for our GPCR program, as well as an additional \$5.0 million grant award from the Life Sciences Discovery Fund Authority, or LSDF, that will be paid against expenses that we incur for our GPCR program. In exchange for these payments, we agreed to pay Vulcan and LSDF a portion of net proceeds that we receive from the GPCR program. Pursuant to our agreements with Vulcan and the LSDF, we are required to comply with certain covenants, including ones that require us (1) to use commercially reasonable efforts to screen at least 75% of the currently known human Class A orphan GPCRs within 19 months from the date of the agreements, subject to possible extensions, and (2) to commence a medicinal chemistry effort focused on developing a product candidate with respect to one orphan GPCR and cause at least six employees and consultants to dedicate a substantial portion of their time to such activities. These covenants require us to commit substantial resources to activities that we may, absent such covenants, otherwise elect to abandon or delay in favor of other opportunities or to preserve our cash. Further, if we do not comply with these covenants, Vulcan or LSDF could declare that we are in default, which could significantly harm our business and prospects and could cause our stock price to decline.

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**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 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 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 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 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 we are acquired in a change of control, the acquiring party will be required to assume our rights and obligations under the Vulcan and LSDF agreements. A party that wants to acquire us through a change of control may also be less inclined to do so or not be willing to pay as much to acquire us because of the Vulcan and LSDF agreements.

**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 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 restricts 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.

**LSDF may not fund all of the \$5.0 million grant award.**

We have not yet received all of the \$5.0 million of funding under the grant award we received from LSDF. LSDF's grant award is only paid against certain costs we incur in the GPCR program. If LSDF believes that we have breached our agreement before we have received the entire \$5.0 million available under the grant award, LSDF may refuse to provide us any further funding, in which case we will have fewer resources to advance our GPCR program and to meet the covenants related to our GPCR program set forth in our agreements with Vulcan and LSDF.

**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 compound hits 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 the compound hits or recover our investment. Potential partners may also require that we obtain the issuance of patents protecting the new drug targets and compounds.

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that interact with these 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 GPCRs targets, limiting our ability to successfully commercialize these targets either independently or with a partner.

### **Our ability to pursue the development and commercialization of product candidates 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, or MRC, and Helion Biotech, ApS, or 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 candidate. 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 candidate, 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 product candidates 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 product candidates from our Plasmin and MASP-2 programs depend on third-party developers and manufacturers of biologic drug products.**

Any product candidate from our Plasmin or MASP-2 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 Plasmin or MASP-2 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 product candidates for one of these programs, clinical trials or the development of any such product candidate for that program could be substantially delayed until we can find and qualify a manufacturer, which may increase our development costs, slow down our product development and approval process, delay receipt of product revenue and make it difficult to raise additional capital.

### **Our programs may not produce product candidates that are suitable for clinical trials or that can be successfully commercialized.**

Any product candidates from our preclinical programs, including our GPCR, Plasmin, PDE7, MASP-2 and PDE10 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 product candidates 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, have produced varying results. Further, we cannot be certain that any of our preclinical product development programs will generate product candidates that are suitable for clinical testing. For example, we have not yet generated any product candidates 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 de-orphanized GPCRs that we develop independently, we are unable to develop related product candidates that successfully complete preclinical or clinical testing. We also cannot be certain that any product candidates that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

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**Because we have a number of development programs and are considering a variety of product candidates, we may expend our limited resources to pursue a particular candidate or candidates and fail to capitalize on candidates 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 preclinical development programs and product candidates that we believe are the most promising. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential and may not be able to progress development programs, 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 candidate, we may relinquish valuable rights to that product candidate 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 product candidates and the methods used to manufacture them, and related to therapeutic targets and methods of treatment, as well as successfully defending these patents against potential third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the 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 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 of 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.

Our issued PharmacoSurgery patents have terms that will expire December 12, 2014 and, if our pending PharmacoSurgery patent applications issue as patents, October 20, 2019 for OMS103HP, July 30, 2023 for OMS302 and March 17, 2026 for OMS201, not taking into account any extensions due to potential adjustment of patent terms resulting from USPTO delays. We cannot assure you that any of these patent applications will be found to be patentable, including over our prior art patents, or will issue as patents or of the scope of any claims that may issue from these pending and future patent applications, or the outcome of any proceedings by any

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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 product candidates and materially harm our business.

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

we might not have been the first to make the inventions covered by any of our 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 infringed, invalid or unenforceable under U.S. or foreign laws;

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

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

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

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other 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.



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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 product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our contract manufacturers are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, 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 product candidates, 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 the technology. 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 another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference 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.

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.

### **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.

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**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 except for on the life of Gregory Demopulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, could delay 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.

**Our former chief financial officer has filed a lawsuit against us and our current and former directors, the defense of which may consume our time and resources, harm our reputation and the reputations of our current and former directors, and materially negatively affect our financial position and cause our stock price to decline.**

In December 2008, our former chief financial officer, Richard J. Klein, used our Whistleblower Policy procedures to report to the chairman of our audit committee that we had submitted grant reimbursement claims 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 January 2009, we terminated Mr. Klein's employment for reasons other than this incident. Mr. Klein alleged that he was wrongfully terminated and claimed it was retaliatory. We subsequently voluntarily reported to the NIH Mr. Klein's whistleblower report and the audit committee findings; the NIH confirmed to us in writing that it was satisfied with our handling of the grant matters that were the subject of Mr. Klein's whistleblower report.

On September 21, 2009, Mr. Klein filed a lawsuit against us and some of our current and former directors in the United States District Court for the Western District of Washington, alleging, among other things, that we violated the Federal False Claims Act, wrongfully discharged his employment in violation of public policy and defamed him. Mr. Klein seeks, among other things, damages in an amount to be proven at trial, actual litigation expenses and his reasonable attorneys' fees and damages for loss of future earnings. On January 8, 2010, the court dismissed all of our non-executive directors from the case with prejudice, and on July 27, 2010 Mr. Klein withdrew his defamation claim. On December 8, 2010, Mr. Klein was granted leave to amend his complaint to add a qui tam claim asserted on behalf of the U.S. Government under the Federal False Claims Act. The qui tam

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claim is based on the same NIH grant that was the subject of Mr. Klein's whistleblower report and related NIH grants totaling \$1.3 million. Mr. Klein seeks on behalf of the U.S. Government and himself an award of civil penalties, treble damages and fees and costs. Although we have been advised by outside counsel that we have meritorious defenses to Mr. Klein's allegations, and we are defending against the claims vigorously, neither the outcome of the litigation nor the amount and range of potential damages or exposure associated with the litigation can be assessed with certainty. Further, defending this lawsuit may consume our time and resources, harm our reputation and the reputations of our current and former directors, and materially negatively affect our financial position 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 first-year compliance under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the NASDAQ Stock Market. In addition, on July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say-on-pay and proxy access. The requirements of these 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 used to be 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 controls 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 controls over financial reporting. Section 404 requires us to perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls 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 controls 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 controls over financial reporting are 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 potential 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 product candidates, that reach the market before our product candidates, or that otherwise

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negatively affect the market, we may not achieve commercial success. For example, we are developing PDE10 inhibitors to identify a product candidate for use in the treatment of schizophrenia and other psychotic disorders. Other pharmaceutical companies, many with significantly greater resources than we have, are also developing PDE10 inhibitors for the treatment of schizophrenia and other psychotic disorders and these companies may be further along in development. The failure of a PDE10 inhibitor product candidate from any of our competitors to demonstrate safety or efficacy in clinical trials may negatively reflect on the ability of our PDE10 inhibitor product candidates under development to demonstrate safety and efficacy. In addition, we believe that other companies are attempting to de-orphanize orphan GPCRs. If any of these companies are able to de-orphanize an 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 developed from our product candidates 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 developed from our product candidates;

commercialize competing products before we can launch any products developed from our product candidates;

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 product candidates.

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

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



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testing and surveillance to monitor the safety or efficacy of the product candidate. Later discovery of previously unknown problems with our product candidates or their manufacture, or failure to comply with regulatory requirements, may result in:

restrictions on such product candidates or manufacturing processes;

withdrawal of the product candidates from the market;

voluntary or mandatory recalls;

finest;

suspension of regulatory approvals;

product seizures; or

injunctions or the imposition of civil or criminal penalties.

If we are slow to adapt, 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 product candidates 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 product candidates 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 product candidates 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 product candidates to market, these products may not be considered cost-effective, and the amount reimbursed for any product candidates may be insufficient to allow us to sell our product candidates 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.

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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 product candidates have been approved for marketing, we can provide you no assurances at this time regarding their cost-effectiveness and the amount, if any, or method of reimbursement. Further, we can provide you no assurance that the amounts, if any, reimbursed to surgical facilities for utilization of our surgery-related product candidates or to surgeons for the administration and delivery of these product candidates will be considered adequate to justify the use of these product candidates. There may be significant delays in obtaining reimbursement coverage for newly approved product candidates and we may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payor determines that a product is eligible for reimbursement, coverage may be more limited than the purposes for which the product candidate 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 are challenging the prices charged for medical products. Moreover, eligibility for coverage does not mean that any product candidate 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 product candidates may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time after the receipt of marketing approval for a product candidate. If the reimbursement we are able to obtain for any product candidate 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 candidate's safety and efficacy and could limit our ability to sell one or more product candidates, if approved, by preventing or interfering with commercialization of our product candidates. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain and maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the commercialization of our product candidates 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.**

We completed the initial public offering of shares of our common stock in October 2009 at a price of \$10.00 per share. Subsequently, our common stock has traded as low as \$5.02 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 include:

results from our clinical trial programs, including our ongoing Phase 3 clinical program for OMS103HP for use in ACL reconstruction surgery, our ongoing Phase 2b clinical trial for OMS302 and our ongoing Phase 2 clinical trials for our PPARg program;

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FDA or international regulatory actions, including failure to receive regulatory approval for any of our product candidates;

announcements regarding the progress of our GPCR program;

failure of any of our product candidates, 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 product candidates on a timely basis;

announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;

third-party coverage and reimbursement policies;

additions or departures of key personnel;

commencement of, or our involvement in, litigation;

our ability to meet our repayment and other obligations under our debt facility with Oxford, pursuant to which we borrowed \$10.0 million on October 21, 2010 and have the right to borrow up to an additional \$10.0 million through March 31, 2011;

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 product candidates may be delayed.

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

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 to raise 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 plan to seek to raise additional capital, except for our committed equity line financing facility described below and our debt facility with Oxford, we have no commitments for additional capital and cannot be

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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, 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 product candidates or one or more of our other research and development initiatives. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might be available or to relinquish or license on unfavorable terms our rights to technologies or product candidates 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 committed equity line financing facility, our existing shareholders will experience immediate dilution and, as a result, our stock price may go down.**

In July 2010, we entered into a committed equity line financing facility, or financing arrangement, under which we may 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 4,297,495 shares of our common stock. If we elect to use the financing arrangement, 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 them pursuant to the financing arrangement and such sales could cause the market price of our common stock to decline significantly with advances under the financing arrangement. 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 financing arrangement could be significantly lower than \$40.0 million. Although Azimuth is precluded from short sales of shares acquired pursuant to advances under the financing arrangement, the sale of our common stock under the financing arrangement 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 6.2 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, more difficult and prevent attempts by our shareholders to replace or remove our current management.**

Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of shareholders to fill board vacancies and the ability of our board of directors to issue preferred stock without shareholder approval. In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of shareholders owning ten percent or more of our outstanding voting stock from merging or combining with us.

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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 more 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. 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 13,000 square feet for our principal administrative facility under a lease that expires July 31, 2014, and approximately 4,000 square feet of adjacent administrative facility space under a lease that expires August 31, 2012 and that is extendable until July 31, 2014. We also lease approximately 24,600 square feet for our research and development facility, which includes a modern vivarium, under a lease that expires September 30, 2012, and approximately 2,500 of adjacent research and development facility space on a month-to-month basis. Our administrative and research and development facilities are located in separate buildings in Seattle, Washington. The annual lease payments for these facilities, including common area maintenance and related operating expenses, are approximately \$2.2 million. We believe that the facilities we lease currently are sufficient for our anticipated near-term needs.

### **ITEM 3. LEGAL PROCEEDINGS**

On September 21, 2009, our former chief financial officer, Richard J. Klein, filed a lawsuit against us and some of our current and former directors in the United States District Court for the Western District of Washington. Mr. Klein alleges in his complaint that we, among other things, violated the Federal False Claims Act, wrongfully discharged his employment in violation of public policy and defamed him. Mr. Klein seeks, among other things, damages in an amount to be proven at trial, actual litigation expenses and his reasonable attorneys' fees and damages for loss of future earnings. On October 4, 2009, we filed with the court our amended answer to Mr. Klein's allegations, generally denying his claims and bringing counterclaims against Mr. Klein for breach of contract, misappropriation of trade secrets and breach of fiduciary duty. Mr. Klein filed an answer with the court generally denying our counterclaims. On January 8, 2010, the court dismissed all of our non-executive directors from the case with prejudice, and on July 27, 2010, Mr. Klein withdrew his defamation claim. On December 8, 2010, Mr. Klein was granted leave to amend his complaint to add a qui tam claim asserted on behalf of the U.S. Government under the Federal False Claims Act. The qui tam claim is based on the same NIH grant that was the subject of Mr. Klein's whistleblower report and related NIH grants totaling \$1.3 million. Mr. Klein seeks on behalf of the U.S. Government and himself an award of civil penalties, treble damages and fees and costs. We are vigorously defending ourselves against Mr. Klein's claims and seek, among other things, our attorneys' fees and costs incurred in defending this action.

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In December 2008, Mr. Klein used our Whistleblower Policy procedures to report to the chairman of our audit committee that we had submitted grant reimbursement claims 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 January 2009, we terminated Mr. Klein's employment for reasons other than this incident. We subsequently voluntarily reported to the NIH Mr. Klein's whistleblower report and the audit committee findings; the NIH confirmed to us in writing that it was satisfied with our handling of the grant matters that were the subject of Mr. Klein's whistleblower report. Although we deny Mr. Klein's allegations and believe that we have substantial and meritorious defenses to his claims, neither the outcome of the litigation nor the amount and range of potential damages or exposure associated with the litigation can be assessed with certainty.

**ITEM 4. RESERVED**

**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, 2010</b>	<b>High</b>	<b>Low</b>
1st Quarter	\$ 7.70	\$ 5.45
2nd Quarter	\$ 7.80	\$ 5.02
3rd Quarter	\$ 8.99	\$ 5.78
4th Quarter	\$ 8.50	\$ 6.71
<b>Year Ended December 31, 2009</b>		
4th Quarter (October 8, 2009 through December 31, 2009)	\$ 9.49	\$ 5.27

**Holders**

As of February 28, 2011, there were approximately 290 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 Finance Corporation 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.

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**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, 2010. 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 Securities Exchange Act of 1934, as amended, 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 Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended, 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.

	Year Ended December 31,					Period from June 16, 1994 (Inception) To December 31, 2010
	2010	2009	2008 (in thousands, except share data)	2007	2006	
<b>Consolidated Statements of Operations Data:</b>						
Grant revenue	\$ 2,105	\$ 1,444	\$ 1,170	\$ 1,923	\$ 200	\$ 6,942
Operating expenses:						
Research and development	23,465	16,929	17,850	15,922	9,637	102,628
Acquired in-process research and development					10,891	10,891
General and administrative	8,746	5,273	7,845	10,398	3,625	46,502
Total operating expenses	32,211	22,202	25,695	26,320	24,153	160,021
Loss from operations	(30,106)	(20,758)	(24,525)	(24,397)	(23,953)	(153,079)
Investment income	167	214	661	1,582	1,088	5,544
Interest expense	(1,535)	(2,202)	(335)	(151)	(91)	(4,366)
Loss on extinguishment of debt	(296)					(296)
Other income (expense)	2,519	1,657	372	(125)	179	4,610
Net Loss	\$ (29,251)	\$ (21,089)	\$ (23,827)	\$ (23,091)	\$ (22,777)	\$ (147,587)
Basic and diluted net loss per common share	\$ (1.37)	\$ (2.92)	\$ (8.26)	\$ (10.65)	\$ (12.08)	
Denominator for basic and diluted net loss per common share	21,420,883	7,218,915	2,883,522	2,167,500	1,884,925	

	As of December 31,				
	2010	2009	2008	2007	2006
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	41,993	60,305	19,982	24,082	35,885
Working capital (deficit)	27,880	49,574	(3,083)	16,526	32,277
Total assets	45,704	62,062	21,681	27,162	38,432
Total notes payable	9,755	12,758	16,674	1,010	2,015
Preferred stock warrant liability			1,780	1,562	1,037
Convertible preferred stock			89,168	89,168	85,742
Deficit accumulated in the development stage	(147,587)	(118,336)	(97,247)	(73,420)	(50,329)
Total shareholders' equity (deficit)	20,470	43,145	(91,166)	(69,941)	(53,363)

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### **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 end of Item 1 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, bleeding and disorders of the central nervous system. Our most clinically advanced product candidates are derived from our proprietary PharmacoSurgery platform designed to improve clinical outcomes of patients undergoing arthroscopic, ophthalmological, 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 six ongoing clinical development programs, including four from our PharmacoSurgery platform and two from our addiction franchise. Our most advanced clinical development program is in a Phase 3 clinical program evaluating OMS103HP for arthroscopy in patients undergoing arthroscopic anterior cruciate ligament, or ACL, reconstruction. We expect to announce data from this program during the first quarter of 2011. 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 product candidates and programs, we have retained all manufacturing, marketing and distribution rights.

OMS103HP, our lead PharmacoSurgery product candidate, is in two clinical programs. The first is a Phase 3 clinical program evaluating OMS103HP's safety and ability to improve postoperative joint function and reduce pain following ACL reconstruction surgery. The second program is preparing for Phase 3 clinical trials to evaluate OMS103HP's safety and ability to improve postoperative joint function and reduce pain following arthroscopic partial meniscectomy surgery. We expect to release the results from our ongoing Phase 3 clinical program for ACL reconstruction surgery in the first quarter of 2011. We believe that OMS103HP will, if approved, be the first commercially available drug delivered directly to the surgical site to improve function following arthroscopic surgery.

Our other current PharmacoSurgery product candidates are OMS302, being developed for use during ophthalmological procedures, including cataract and other lens replacement surgery, and OMS201, being developed for use during urological surgery, including uroendoscopic procedures. We are conducting a Phase 2b clinical trial for OMS302 to assess the effect of the mydriatic API and the anti-inflammatory API in a full-factorial design. We expect to release the results from this Phase 2b study during the first quarter of 2011. During the fourth quarter of 2010, we successfully completed a Phase 1/Phase 2 clinical trial of in patients undergoing ureteroscopic removal of ureteral or renal stones. The data showed that OMS201 was safe and well tolerated by the patients in this study.

In addition to our PharmacoSurgery platform, we have a pipeline of additional product development programs targeting inflammation, bleeding and the CNS. In our PPARg program, we are developing proprietary compositions that include PPARg agonists for the treatment and prevention of addiction to substances of abuse,

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which may include opioids, nicotine and alcohol. The National Institute on Drug Abuse, or NIDA, is funding substantially all of the costs of two Phase 2 clinical study evaluating a PPAR $\gamma$  agonist in the treatment of addiction to oxycontin and heroin. These Phase 2 clinical studies are being conducted by researchers at the New York State Psychiatric Institute, or NYSPI.

In our Plasmin program, we are advancing novel antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma. Our PDE7 program is based on our discoveries of previously unknown links between PDE7 and any movement disorder, such as Parkinson's disease, as well as addiction and compulsive disorders, and we are developing proprietary compounds for the treatment of these and other disorders. In our mannan-binding lectin-associated serine protease-2, or MASP-2, program, we are developing proprietary MASP-2 antibody therapies to treat disorders caused by complement-activated inflammation. In our PDE10 program, we are developing proprietary compounds to treat schizophrenia and other psychotic disorders.

In our GPCR program, we are working to complete high-throughput de-orphanization of orphan GPCRs, or the identification of synthetic molecules that bind the receptors, and to develop product candidates that act at these new potential drug targets. We have already announced that we have identified and confirmed sets of compounds that interact selectively with, and modulate signaling of a series of orphan GPCRs, including orphans linked to squamous cell carcinoma (GPR87), pancreatic cancer (GPR182), obesity (GPR85), appetite control (GPR101) and cognitive disorders (GPR12). During the fourth quarter of 2010, we entered into an 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. Also during the same quarter, we entered into an agreement with the State of Washington's Life Sciences Discovery Fund Authority, or LSDF, under which we received a \$5.0 million grant award that will be paid against expenses that we incur for our GPCR program. In exchange for these payments, we agreed to pay to Vulcan and LSDF a portion of net proceeds that we receive from the GPCR program. We also issued to the Vulcan affiliate three five-year warrants to purchase our common stock, each for 133,333 shares, with exercise prices of \$20, \$30 and \$40 per share, respectively. Following the receipt of the \$20.0 million from Vulcan, we purchased from Patobios Limited, or Patobios, intellectual property assets related to an assay technology for use in the GPCR program. The purchase price for these assets was approximately \$10.8 million Canadian dollars, or CAD, of which approximately \$7.8 million CAD (\$7.6 million USD) was paid in cash and \$3.0 million CAD (\$3.2 million USD) was paid in shares of our common stock.

We have incurred significant losses since our inception. As of December 31, 2010, our accumulated deficit was \$147.6 million and total shareholders' equity was \$20.5 million. We recognized net losses of \$29.3 million, \$21.1 million and \$23.8 million for the years ended December 31, 2010, 2009 and 2008, 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 product candidates. Compared to 2010, we expect our net losses to increase as we continue to advance our clinical trials, expand our research and development efforts and add personnel as well as laboratory and office space for our anticipated growth. In addition, if we receive positive data from our Phase 3 program evaluating OMS103HP in ACL reconstruction surgery, our net losses may increase further as a result of expanded commercialization activities.

On October 13, 2009, we completed our initial public offering of 6,820,000 shares of our common stock at a price of \$10.00 per share. Net cash proceeds from the public offering were approximately \$61.8 million, after deducting underwriting discounts and commissions and offering expenses paid or payable by us following the offering.

### *Revenue*

We have recognized \$6.9 million of revenue from inception through December 31, 2010, consisting of grant funding from third parties and revenue recognized in connection with our GPCR program funding agreements with Vulcan and LSDF. Other than grant funding, we do not expect to receive any revenue from our product candidates until we receive regulatory approval and commercialize the product candidates or until we potentially

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enter into collaborative agreements with third parties for the development and commercialization of our product candidates. We continue to pursue government and private grant funding for our product candidates 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 trials 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 as 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, contract research organizations, clinical trial sites, and collaborators or licensors;

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 internal resources, employees and infrastructure are not directly tied to any individual research project and are typically deployed across multiple projects. Through our clinical development programs, we are advancing our product candidates in parallel for multiple therapeutic indications and, through our preclinical development programs, we are seeking to develop potential product candidates for additional disease indications. Due to the number of ongoing projects and our ability to utilize resources across several projects, we do not record or maintain information regarding the costs incurred for our research and development programs on a program-specific basis.

Research and development expenses from inception (July 16, 1994) to December 31, 2010 were \$102.6 million. 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,		
	2010	2009	2008
	(in thousands)		
<b>Clinical Research and Development</b>			
Salaries, benefits, and related costs	\$ 3,939	\$ 3,649	\$ 3,521
Clinical trials	4,350	2,270	3,525
Manufacturing services, consulting, laboratory supplies, and other costs	4,676	1,887	2,080
Other costs	1,085	1,106	1,049
Stock-based compensation	527	502	590
<b>Total Clinical Research and Development Expenses</b>	<b>14,577</b>	<b>9,414</b>	<b>10,765</b>
<b>Preclinical Research and Development</b>			
Salaries, benefits, and related costs	3,067	2,523	2,572
Research and preclinical studies, consulting, laboratory supplies, and other costs	3,926	3,130	2,774
Other costs	1,451	1,485	1,346
Stock-based compensation	444	377	393
<b>Total Preclinical Research and Development Expenses</b>	<b>8,888</b>	<b>7,515</b>	<b>7,085</b>

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Total Research and Development Expenses	\$ 23,465	\$ 16,929	\$ 17,850
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Clinical research and development costs consist of clinical trials, manufacturing services, regulatory activities and related personnel costs, and other costs such as rent, utilities, depreciation and stock-based compensation. Preclinical research and development costs consist of our research activities, preclinical studies, related personnel costs and laboratory supplies, and other costs such as rent, utilities, depreciation and stock-based compensation.

At this time, due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates 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 candidate, as well as ongoing assessments of each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We expect our research and development expenses to increase in the future as we continue the advancement of our clinical trials and preclinical product development programs as well as accelerate and expand our research efforts in our GPCR program.

The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates 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 expense to increase and, in turn, have a material adverse effect on our operations. We do not expect any of our current product candidates to be commercially available before 2012, 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.

### *General and Administrative Expenses*

General and administrative expenses consist principally of salaries and related costs for personnel in executive, legal, finance, accounting, business development, information technology and human resource functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent costs and professional fees for legal, consulting and audit services. We expect our general and administrative expenses to increase in the future as we add additional employees and facilities to support our anticipated growth as a public company. In addition, if we receive positive data from our Phase 3 program evaluating OMS103HP in ACL reconstruction surgery, our net losses may increase further as a result of expanded commercialization activities.

### *Investment Income*

Investment income consists of realized gains on sales of investments and interest earned on our cash, cash equivalents, and short-term investments.

### *Interest Expense*

Interest expense consists of interest on our notes payable and the amortization of the related discount.

### *Loss on Extinguishment of Debt*

Loss on extinguishment of debt consists of losses incurred as a result of the refinance of the notes payable to BlueCrest Venture Finance Master Fund Limited, or BlueCrest.

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### *Other Income (Expense)*

Other income (expense) consists primarily of income received from the Qualifying Therapeutic Discovery Project Program, rental income received under subleases for use of a portion of our vivarium and laboratory facility and changes in the fair value of our preferred stock warrant liability.

### *Income Taxes*

As of December 31, 2010, we had federal net operating loss carryforwards and research and development tax credit carryforwards of approximately \$117.1 million and \$3.2 million, respectively. Our net operating loss and research and development tax credit carryforwards began to expire in 2009 and should continue to expire through 2030 unless utilized prior to such dates. 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 Internal Revenue Code of 1986, as amended, or the Code, has occurred or may occur in the future. In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statement of operations.

## **Critical Accounting Policies and Significant Judgments and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of any contingent assets and liabilities at the date of the financial statements, as well as reported revenue and expenses during the reporting periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. 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 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 management judgment and estimates about matters that are uncertain:

revenue recognition;

research and development expenses, primarily clinical trial expenses;

stock-based compensation;

fair value measurement of financial instruments.

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

### *Revenue Recognition*

Our revenue since inception relates to grant funding from third parties and revenue recognized in connection with funding from Vulcan and LSDF. We recognize revenue when the related qualified research and development expenses are incurred or services are provided up to the limit of the approved funding amounts.

The accounting standards for revenue provide a framework for accounting for revenue arrangements. A variety of factors are considered in determining the appropriate method of revenue recognition under these 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.

**Table of Contents***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, contract research organizations 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; and third-party supplier expenses including laboratory and other supplies. 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*

We account for stock-based compensation under applicable accounting standards, which requires that the measurement and recognition of compensation expense for all future share-based payments made to employees and directors be based on estimated fair values. We are using the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. We estimate the fair value of our share-based awards to employees and directors using the Black-Scholes option-valuation model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense 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.

*Fair Value Measurement of Financial Instruments*

Our financial assets and liabilities are measured at fair value, 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.

In determining the fair value of our financial assets and liabilities, we used various valuation approaches. The guidance establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources such as quotes in active markets. Unobservable inputs are those in which little or no market data exists and reflect our assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment.

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Whenever the estimated fair value of any of our available-for-sale securities is less than their related cost, we perform an impairment analysis to determine the classification of the impairment as temporary or other-than-temporary. A temporary impairment results in an unrealized loss being recorded in the other comprehensive income component of shareholders' equity. Such an unrealized loss does not affect net loss for the applicable accounting period. However, an other-than-temporary impairment charge is recorded as a realized loss in the consolidated statement of operations and increases net loss for the applicable accounting period. The primary factors we consider to differentiate our impairments between temporary and other-than-temporary impairments include the length of the time and the extent to which the market value has been less than cost, the financial condition and near-term prospects of the issuer and our intent and ability to retain our investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

We believe that the values assigned to our available-for-sale securities as of December 31, 2010, 2009 and 2008 are fairly stated in accordance with GAAP and are based upon reasonable estimates and assumptions. In addition, we believe that the cost basis for our available-for-sale securities are recoverable in all material respects.

## **Results of Operations**

### *Comparison of Years Ended December 31, 2010 and December 31, 2009*

**Revenue.** Revenue was \$2.1 million in 2010 compared to \$1.4 million in 2009. The increase was primarily due to the recognition of revenue in connection with funding from Vulcan and LSDF for our GPCR program and additional revenue recognized in connection with our NIH grants. These increases were partially offset by a decrease in revenue recognized from grants from The Michael J. Fox Foundation, or MJFF, for our PDE7 program.

**Research and Development Expenses.** Research and development expenses were \$23.5 million in 2010 compared to \$16.9 million in 2009. The increase was primarily due to higher consulting costs associated with our OMS103HP program, higher clinical trial costs associated with our Phase 2b clinical trial evaluating OMS302, higher contract service costs associated with several of our clinical and preclinical programs and an increase in employee expenses.

**General and Administrative Expenses.** General and administrative expenses were \$8.7 million in 2010 compared to \$5.3 million in 2009. The increase was primarily due to higher costs associated with being a public company and an increase in employee expenses.

**Investment Income.** Investment income was \$167,000 in 2010 compared to \$214,000 in 2009. The decrease is due to lower market interest rates in 2010 compared to 2009.

**Interest Expense.** Interest expense was \$1.5 million in 2010 compared to \$2.2 million in 2009. Interest expense decreased in 2010 primarily due to lower interest expense on our borrowings from BlueCrest and lower amortization of the related discount and debt issuance costs. This was partially offset by the recognition of \$208,000 of the remaining unamortized BlueCrest debt issuance costs and debt discount in connection with the Oxford refinance.

**Loss on Extinguishment of Debt.** The loss on extinguishment of debt was \$296,000 in 2010 and relates entirely to losses incurred as a result of the refinancing of our borrowings from BlueCrest.

**Other Income (Expense).** Other income was \$2.5 million in 2010 compared to \$1.7 million in 2009. The increase in other income is primarily due to income received from the Qualifying Therapeutic Discovery Project Program partially offset by no warrant revaluation in 2010.

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### *Comparison of Years Ended December 31, 2009 and December 31, 2008*

*Revenue.* Revenue was \$1.4 million in 2009 compared to \$1.2 million in 2008. The increase was primarily due to higher grant revenue recognized under a grant from MJFF for our PDE7 program, and was partially offset by the recognition of decreased revenue in connection with grants from the NIH.

*Research and Development Expenses.* Research and development expenses were \$16.9 million in 2009 compared to \$17.9 million in 2008. The decrease was primarily due to a reduction in contract service costs associated with several of our clinical and preclinical programs and a reduction of clinical trial costs due to the prior completion of enrollment in the Phase 2 clinical study of OMS103HP for arthroscopic meniscectomy surgery. This was partially offset by an increase of \$903,000 in technology acquisition option fees related to our right to purchase assets from Patobios for use in our GPCR program.

*General and Administrative Expenses.* General and administrative expenses were \$5.3 million in 2009 compared to \$7.8 million in 2008. The decrease was primarily due to the write-off of \$1.9 million of deferred offering costs related to a delay in our initial public offering during the 2008 period and lower stock-based compensation expense in 2009.

*Investment Income.* Investment income was \$214,000 in 2009 compared to \$661,000 in 2008. The decrease is due to lower market rates in 2009 compared to 2008.

*Interest Expense.* Interest expense was \$2.2 million in 2009 compared to \$335,000 in 2008. Interest expense increased in 2009 due to interest expense on our borrowings from BlueCrest and the amortization of the related discount.

*Other Income (Expense).* Other income was \$1.7 million in 2009 compared to other income of \$372,000 in 2008. The increase in other income is primarily due to the revaluation of the fair value of warrants in 2009 and income from new sublease tenants.

## **Liquidity and Capital Resources**

From inception to December 31, 2010, we have financed our operations primarily through private and public placements of equity securities for proceeds totaling \$139.2 million, through two debt facilities with loan proceeds totaling \$27.0 million, \$9.0 million of which was used to pay off the remaining balance of the first facility, and our GPCR program funding agreement with Vulcan pursuant to which we received \$20.0 million. The proceeds have been used to fund our operations. As of December 31, 2010, we had \$42.0 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.

On October 21, 2010, we entered into an agreement with Vulcan pursuant to which we received \$20.0 million for our GPCR program. Also on October 21, 2010, we entered into an agreement with the State of Washington's Life Sciences Discovery Fund Authority under which we received a \$5.0 million grant award that will be paid as reimbursement of expenses we incur and equipment purchases we make for our GPCR program. In addition, we agreed to purchase from Patobios intellectual property assets related to a proprietary cellular redistribution assay for consideration consisting of approximately \$10.8 million CAD. We completed the acquisition of these assets on November 22, 2010 by paying to Patobios \$7.8 million CAD (\$7.6 million USD) in cash and the remaining \$3.0 million CAD (\$3.2 million USD) in the form of 379,039 shares of our common stock. Because Vulcan provided the funding for these assets, such assets have a zero cost basis on our balance sheet.

In addition, on October 21, 2010 we entered into a \$20.0 million debt facility with Oxford Finance Corporation, or Oxford, pursuant to which Oxford has agreed to lend us up to \$20.0 million in two tranches of

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\$10.0 million each. Upon signing the agreement, we borrowed the first tranche of \$10.0 million, approximately \$9.0 million of which we used to repay all outstanding amounts, including a 1.0% prepayment fee, due under our loan and security agreement with BlueCrest. Under our agreement with Oxford, at any time before March 31, 2011 we may, at our sole option, borrow from Oxford the second tranche of \$10.0 million, subject to our satisfaction of specified conditions precedent described in the agreement.

Also, on October 29, 2010, we were awarded grants totaling approximately \$1.7 million from the U.S. government pursuant to the Qualifying Therapeutic Discovery Project Program. We received approximately \$1.5 million in 2010, which was recorded as other income, net, and we expect to receive the remaining \$236,000 during the first quarter of 2011.

### *Comparison of Years Ended December 31, 2010 and December 31, 2009*

*Operating Activities.* Net cash used in operating activities was \$14.5 million and \$19.0 million for the years ended December 31, 2010 and 2009, respectively. Expenditures related to operating activities were a result of research and development expenses, clinical trial costs, and general and administrative expenses in support of our operations. Higher operating expenses in 2010 were offset by an increase in non-cash stock-based compensation and an increase in deferred revenue related to the Vulcan funding.

*Investing Activities.* Net cash provided by investing activities was \$19.9 million for the year ended December 31, 2010 and net cash used in investing activities was \$52.4 million for the comparable period in 2009. Since our inception, investing activities, other than purchases and maturities of short-term and long-term investments, consist primarily of purchases of property and equipment and, in 2010, the acquisition, and subsequent reimbursement by Vulcan of the purchase price, of intellectual property assets from Patobios. For the year ended December 31, 2009, proceeds from the sales of investments consisted primarily of investments purchased with proceeds from our IPO. Cash flows from investing activities primarily reflect large amounts of cash used to purchase short-term investments and receipts from the sale and maturity of short-term investments. These amounts primarily relate to shifts between cash and cash equivalents and short-term investments. 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 an understanding of our liquidity and capital resources.

*Financing Activities.* Net cash used in financing activities was \$3.0 million for the year ended December 31, 2010 and net cash provided by financing activities was \$59.5 million for the year ended December 31 and 2009. Net cash used in 2010 was primarily due to proceeds received from our loan from Oxford, partially offset by the payoff of our BlueCrest loan. Net cash provided for 2009 was due to the sale of common stock in our initial public offering in October 2009 for aggregate net proceeds of \$61.8 million.

### *Comparison of Years Ended December 31, 2009 and December 31, 2008*

*Operating Activities.* Net cash used in operating activities was \$19.0 million and \$19.7 million for the years ended December 31, 2009 and 2008, respectively. Expenditures related to operating activities were a result of research and development expenses, clinical trial costs, and general and administrative expenses in support of our operations. The decrease in net cash used in operating activities for 2009 was also impacted by lower non-cash stock-based compensation and a 2008 write-off of deferred offering costs.

*Investing Activities.* Net cash used in investing activities was \$52.4 million for the year ended December 31, 2009, and net cash provided by investing activities was \$10.6 million for the comparable period in 2008. Investing activities for the year ended December 31, 2009 consisted primarily of investments purchased with proceeds from our IPO, partially offset by the shift of investments to cash and cash equivalents to fund our operations.

*Financing Activities.* Net cash provided by financing activities was \$59.5 million and \$15.9 million for the years ended December 31, 2009 and 2008, respectively. The net cash provided for 2009 was due to the sale of

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common stock in our initial public offering in October 2009 for aggregate net proceeds of \$61.8 million. Net cash provided in 2008 was primarily due to the borrowing of \$17.0 million under our loan from BlueCrest.

In July 2010, we entered into an equity line financing facility with Azimuth Opportunity, Ltd., or Azimuth, pursuant to which we may sell up to \$40.0 million of our shares of common stock over a 24-month term. From time to time over the 24-month term, and in our sole discretion, we may 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 4.00% to 7.00%, based on a minimum price that we solely specify. In addition, in our sole discretion, but subject to certain limitations, we may require Azimuth to purchase a percentage of the daily trading volume of our common stock for each trading day during the draw down period. 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 4,297,495 shares in connection with the committed equity line financing facility.

In partial consideration for Azimuth's execution and delivery of the purchase agreement for the facility, we paid to Azimuth \$100,000 in cash. We also paid \$35,000 of Azimuth's legal fees and expenses. All costs were charged to general and administrative expense as incurred. No additional legal fees incurred by Azimuth are payable by us in connection with any sale of shares to Azimuth. In connection with this facility, we entered into a placement agent agreement with Reedland Capital Partners, or Reedland. We have agreed to pay Reedland, upon each sale of our common stock to Azimuth, a fee equal to 0.5% of the aggregate dollar amount of common stock purchased by Azimuth upon settlement of each such sale.

On October 21, 2010, we entered into a \$20.0 million debt facility with Oxford pursuant to which Oxford agreed to lend us up to \$20.0 million in two tranches of \$10.0 million each. Upon signing the agreement, we borrowed the first tranche of \$10.0 million, or Tranche 1, approximately \$9.0 million of which we used to repay all outstanding amounts, including a 1.0% prepayment fee, due under our loan and security agreement with BlueCrest. Upon payment of the approximately \$9.0 million to BlueCrest on October 21, 2010, all of our liabilities to BlueCrest were paid in full, and all commitments of BlueCrest to us under the loan agreement were terminated.

Under the terms of our agreement with Oxford, at any time before March 31, 2011 we may, at our sole option, borrow from Oxford the second tranche of \$10 million, or Tranche 2, subject to our satisfaction of specified conditions precedent described in the agreement. We may use the proceeds remaining from Tranche 1 and, if borrowed, Tranche 2, for working capital and to fund our general business requirements. Interest on Tranche 1 accrues at an annual fixed rate of 8.55% and, if borrowed, interest on Tranche 2 will accrue at an annual fixed rate equal to the 3-month LIBOR rate in effect immediately prior to the funding of Tranche 2 plus 8.25%. Payments due under Tranche 1 and, if borrowed, Tranche 2, are interest only, payable monthly, in arrears, through October 31, 2011. Beginning November 1, 2011, 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, October 21, 2014.

The Oxford 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, and repurchase stock, in each case subject to customary exceptions for a credit facility of this size and type. The loan agreement contains no cash covenant. The loan agreement also contains

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customary events of default that include, among other things, non-payment defaults, inaccuracy of representations and warranties, covenant defaults, material adverse change default (as defined in the agreement), cross default to material indebtedness, bankruptcy and insolvency defaults, material judgment defaults, and a change of control default. We have no indication that we are in default of the material adverse change clause, and no scheduled loan payments have been accelerated as a result of this provision. The occurrence of an event of default could result in the acceleration of the obligations under the loan agreement. Under certain circumstances, a default interest rate will apply on all obligations during the existence of an event of default at a per annum rate equal to 5.0% above the otherwise applicable interest rate.

We made a one-time facility fee payment to Oxford of \$50,000 for Tranche 1 and, if we borrow Tranche 2, we will be required to make a second facility fee payment of \$50,000. Upon the last payment date of the amounts borrowed under from Oxford, we will be required to pay Oxford a final payment fee equal to 5.0% of Tranche 1 (\$500,000) and, if borrowed, 5.0% of Tranche 2, provided that the percentage for Tranche 2 will decrease by 0.20% for each month that lapses between the date of the Oxford loan agreement and the funding date for Tranche 2. As security for our obligations under the loan agreement, we granted Oxford a security interest in substantially all of our assets, excluding intellectual property. We may prepay all, but not less than all, of the outstanding principal and accrued and unpaid interest under the loan agreement at any time upon prior notice to Oxford and the payment of a fee equal to 1.0% of the then-outstanding principal amount. In connection with the Oxford loan agreement, we incurred debt issuance costs of \$169,000.

In December 2006, we entered into a funding agreement with The Stanley Medical Research Institute, or SMRI, to develop a proprietary product candidate 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. Through December 31, 2010, we had received \$5.7 million from SMRI, of which \$3.2 million was recorded as equity funding, \$2.3 million was recorded as revenue, and \$227,000 remains in deferred revenue.

In May 2010, we entered into an additional agreement with MJFF to provide funding for a study of PDE7 inhibitors for the treatment of Parkinson's disease. The agreement was for a six-month period and provides funding of actual costs incurred up to a total of \$76,000. We received a payment of \$38,000 in July 2010. We expect to receive the final payment of \$38,000 in the first quarter of 2011.

### *Funding Requirements*

We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months. We base this estimate on assumptions that may prove to be wrong and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, 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 clinical trials for OMS103HP, OMS302, OMS201 and our PPAR $\gamma$  program;

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 scope, rate of progress, results and costs of our preclinical testing, clinical trials and other research and development activities for additional product candidates;

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the terms and timing of payments of any collaborative or licensing agreements that we have or may establish, including pursuant to our agreements with Daiichi Sankyo Co., Ltd., Helion Biotech, ApS, LSDF, North Coast Biologics and Vulcan;

market acceptance of our approved products;

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

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

the number and characteristics of product candidates that we pursue;

the cost of establishing clinical and commercial supplies of our product candidates;

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;

our degree of success in commercializing OMS103HP and other product candidates; and

the extent to which we draw down funds under our committed equity line financing facility with Azimuth or pursuant to our loan agreement with Oxford.

We do not anticipate generating revenue from the sale of our product candidates until 2012 at the earliest. We expect our continuing operating losses to result in an increasing total amount of cash used in operations over the next several years. To the extent our capital resources are insufficient 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 Opportunity, Ltd. and our loan agreement with Oxford, we currently do not have any commitments for future external funding. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, 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 product candidates 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. In addition, any future equity funding will dilute the ownership of our equity investors.

## **Contractual Obligations and Commitments**

The following table presents a summary of our contractual obligations and commitments as of December 31, 2010.

	Payments Due Within			
	1 Year	2-3 Years	4-5 Years	Total

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			(in thousands)		More than 5 Years
Operating leases	\$ 1,568	\$ 1,690	\$ 238	\$	\$ 3,496
Capital leases (principal and interest)	48	100	81		229
License maintenance fees	7	14	14	130	165
Notes payable (principal and interest)	1,413	7,536	3,137		12,086
Total	\$ 3,036	\$ 9,340	\$ 3,470	\$ 130	\$ 15,976

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We may also be required to make royalty and milestone payments under the following agreements with third parties 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:

Pursuant to our agreement with SMRI, beginning the first calendar year after commencement of commercial sales of a product candidate from our PDE10 program, we will be obligated to pay royalties to SMRI 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 that we have received as of December 31, 2010, the maximum amount of royalties payable to SMRI is \$12.8 million.

Under our antibody discovery and development agreement with North Coast Biologics, LLC, we may be required to pay a low single-digit percentage royalty on any net sales of a product containing an antibody developed by North Coast under the agreement. Upon the achievement of certain development events, such as the filing of an IND, initiation of clinical trials and the receipt of marketing approval, we also may be required to make additional milestone payments to North Coast of up to \$4.0 million for a MASP-2 antibody and \$4.1 million per additional target antibody that we may select under the agreement.

Pursuant to our patent assignment agreement with Roberto Ciccocioppo, Ph.D. under which we acquired assets for our PPARg program, we may be required to pay a low single-digit percentage royalty on any net sales of a product from our PPARg program that is covered by any patents that issue from the patent application we acquired from Dr. Ciccocioppo. 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 also may be required to make total milestone payments of up to \$3.8 million upon the achievement of certain development events, such as the initiation of clinical trials and receipt of marketing approval.

Under our PDE7 inhibitor license agreement with Daiichi Sankyo Co., Ltd., we have agreed to make milestone payments to Daiichi Sankyo of up to an aggregate total of \$30.2 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 received by us from the sublicensee.

Pursuant to our exclusive license agreement with Helion Biotech, ApS, or Helion, we agreed to make development and sales milestone payments to Helion of up to \$6.9 million upon the achievement of certain events related to our MASP-2 program, such as the filing of an 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 from us a low single-digit percentage royalty of any net sales of a MASP-2 inhibitor product that is covered by the patents licensed by us under the agreement.

Pursuant to our agreements with Vulcan and LSDF, we agreed to pay Vulcan and LSDF tiered percentages of the net proceeds, if any, derived from our 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. After we have received approximately \$1.5 billion of cumulative net proceeds, the percentage rate payable to Vulcan and LSDF in the aggregate decreases to one percent.

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### **Related-Party Transactions**

We conduct research using the services of one of our founders, Pamela Pierce Palmer, M.D., Ph.D. Costs incurred for the years ended December 31, 2010, 2009 and 2008 totaled \$5,000 per year and \$455,000 for the period from inception (June 16, 1994) through December 31, 2010. In 2007, we granted Dr. Palmer an option to purchase 20,408 shares of common stock and recognized \$51,000, \$(15,000) and \$57,000 of non-cash stock compensation expense (benefit) associated with this option for the years ended December 31, 2010, 2009 and 2008, respectively, and \$136,000 for the period of inception (June 16, 1994) through December 31, 2010.

### **Recent Accounting Pronouncements**

In October 2009, the Financial Accounting Standards Board, or FASB, issued new guidance for multiple-deliverable revenue arrangements. The new guidance addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence; (b) third-party evidence; or (c) estimates. This guidance also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling-price method. In addition, this guidance significantly expands required disclosures related to a vendor's multiple-deliverable revenue arrangements. We expect to adopt this guidance on January 1, 2011 and to apply it prospectively for revenue arrangements entered into or materially modified after the date of adoption. The impact of the above guidance will be dependent on the terms and structure of revenue generating contracts negotiated in the future.

In January 2010, the FASB issued guidance that requires reporting entities to make new disclosures about recurring or nonrecurring fair-value measurements including significant transfers into and out of Level 1 and Level 2 fair value measurements and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. The guidance was effective in 2010, except for Level 3 reconciliation disclosures that are effective for annual periods beginning after December 15, 2010. The adoption of this guidance did not and is not expected to have a material impact on our consolidated financial statements.

In March 2010, FASB issued new guidance for recognizing revenue under the milestone method. This new guidance allows an entity to make a policy election to recognize a substantive milestone in its entirety in the period in which the milestone is achieved. The new guidance also requires an entity that makes this policy election to disclose the following: (a) a description of the overall arrangement; (b) a description of each milestone and related contingent consideration; (c) a determination of whether each milestone is considered substantive; (d) the factors considered in determining whether the milestone is substantive; and (e) the amount of consideration recognized during the period for milestones. We expect to adopt this guidance on January 1, 2011 and to apply it prospectively for revenue arrangements entered into or materially modified after the date of adoption. The impact of the above guidance will be dependent on the terms and structure of revenue generating contracts negotiated in the future.

### **Off-Balance Sheet Arrangements**

Since our inception, we have not engaged in any off-balance sheet arrangements.

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

Our exposure to market risk is primarily confined to our investment securities and notes payable. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality. As of December 31, 2010, we had cash, cash equivalents and short-term investments of \$42.0 million. We have invested these funds in highly liquid, investment-grade securities in accordance with our investment policy. The securities in our investment

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portfolio are not leveraged and are classified as available for sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates and with our current portfolio of short term investments, we are not exposed to potential loss due to changes in interest rates.

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

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

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

None.

### **ITEM 9A. CONTROLS AND PROCEDURES**

#### **Disclosure Controls and Procedures**

Our management, with the participation of our principal executive and principal financial officers, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2010. 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, 2010, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### **Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management, with the participation of our principal executive and principal financial officer, conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2010. 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, 2010.

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The effectiveness of the our internal control over financial reporting as of December 31, 2010 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report that appears herein.

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during our fourth fiscal quarter of 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**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, 2010 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, 2010, 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, 2010 and 2009, and the related consolidated statements of operations, convertible preferred stock and shareholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2010 and for the period from June 16, 1994 (inception) through December 31, 2010 of Omeros Corporation and our report dated March 15, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington

March 15, 2011

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**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 2011 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 2011 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 2011 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, 2010:

	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)	1,233,237	\$ 6.54	1,079,572
Second Amended and Restated 1998 Stock Option Plan	2,323,073	\$ 1.28	0
nura, inc. 2003 Stock Option Plan	2,981	\$ 10.63	0
<i>Equity compensation plans not approved by security holders:</i>			
Stock Option Grant to Gregory A. Demopoulos, M.D. (2)	1,542	\$ 0.52	0
Stock Option Grant to Pamela Pierce Palmer M.D., Ph.D. (2)	28,459	\$ 0.52	0
<i>Total</i>	3,589,292	\$ 3.09	1,079,572

(1)

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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, 2011, an additional 1,096,041 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.

- (2) On December 11, 2001 we granted individual option awards to two of our founders to purchase shares of our common stock. These option awards were fully vested upon grant and are exercisable until December 11, 2011.

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**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 2011 Annual Meeting of Shareholders and is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2011 Annual Meeting of Shareholders and is incorporated herein by reference.

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**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 15, 2011

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

Signature	Title	Date
/s/ GREGORY A. DEMOPULOS, M.D.  Gregory A. Demopulos, M.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer, Principal Accounting Officer and Principal Financial Officer)	March 15, 2011
/s/ RAY ASPIRI  Ray Aspiri	Director	March 15, 2011
/s/ THOMAS J. CABLE  Thomas J. Cable	Director	March 15, 2011
/s/ PETER A. DEMOPULOS, M.D.  Peter A. Demopulos, M.D.	Director	March 15, 2011
/s/ LEROY E. HOOD, M.D., Ph.D.  Leroy E. Hood, M.D., Ph.D.	Director	March 15, 2011
/s/ DANIEL K. SPIEGELMAN  Daniel K. Spiegelman	Director	March 15, 2011
/s/ JEAN-PHILIPPE TRIPET  Jean-Philippe Tripet	Director	March 15, 2011

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**OMEROS CORPORATION**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders of Omeros Corporation

We have audited the accompanying consolidated balance sheets of Omeros Corporation (a development stage company) as of December 31, 2010 and 2009, and the related statements of operations, convertible preferred stock and shareholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2010 and for the period from June 16, 1994 (inception) through December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Omeros Corporation (a development stage company) at December 31, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, and for the period from June 16, 1994 (inception) through December 31, 2010, 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, 2010, 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 15, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Seattle, Washington

March 15, 2011

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**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**CONSOLIDATED BALANCE SHEETS**  
**(In thousands except share and per share data)**

	December 31, 2010	2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,278	\$ 820
Short-term investments	38,715	59,485
Grant and other receivables	1,479	248
Prepaid expenses and other current assets	282	111
Total current assets	43,754	60,664
Property and equipment, net	1,622	1,086
Restricted cash	193	193
Other assets	135	119
Total assets	\$ 45,704	\$ 62,062
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,398	\$ 2,620
Accrued expenses	5,067	2,837
Deferred revenue	8,014	702
Current portion of notes payable	395	4,931
Total current liabilities	15,874	11,090
Notes payable, less current portion	9,360	7,827
Commitments and contingencies		
Shareholders' equity		
Preferred stock, par value \$0.01 per share: authorized shares 20,000,000; issued and outstanding none		
Common stock, par value \$0.01 per share:		
Authorized shares and 150,000,000 at December 31, 2010 and 2009;		
Issued and outstanding shares 21,920,836 and 21,285,577 at December 31, 2010 and 2009, respectively	219	213
Additional paid-in capital	167,838	161,227
Accumulated comprehensive income		41
Deficit accumulated during the development stage	(147,587)	(118,336)
Total shareholders' equity	20,470	43,145
Total liabilities and shareholders' equity	\$ 45,704	\$ 62,062

See notes to consolidated financial statements

**Table of Contents****OMEROS CORPORATION****(A Development Stage Company)****CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except share and per share data)**

	<b>Year Ended December 31,</b>			<b>Period from June 16, 1994 (Inception) through December 31, 2010</b>
	<b>2010</b>	<b>2009</b>	<b>2008</b>	
Grant revenue	\$ 2,105	\$ 1,444	\$ 1,170	\$ 6,942
Operating expenses:				
Research and development	23,465	16,929	17,850	102,628
Acquired in-process research and development				10,891
General and administrative	8,746	5,273	7,845	46,502
Total operating expenses	32,211	22,202	25,695	160,021
Loss from operations	(30,106)	(20,758)	(24,525)	(153,079)
Investment income	167	214	661	5,544
Interest expense	(1,535)	(2,202)	(335)	(4,366)
Loss on extinguishment of debt	(296)			(296)
Other income, net	2,519	1,657	372	4,610
Net loss	\$ (29,251)	\$ (21,089)	\$ (23,827)	\$ (147,587)
Basic and diluted net loss per common share	\$ (1.37)	\$ (2.92)	\$ (8.26)	
Weighted-average shares used to compute basic and diluted net loss per common share	21,420,883	7,218,915	2,883,522	

See notes to consolidated financial statements

**Table of Contents****OMEROS CORPORATION****(A Development Stage Company)****CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND****SHAREHOLDERS EQUITY (DEFICIT)****(In thousands, except share and per share data)**

	Convertible Preferred Stock		Common Stock		Additional	Accumulated Other Comprehensive	Deferred	Notes	Deficit	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Income (Loss)	Stock-Based Compensation	Receivable from Related Party	Accumulated During the Development Stage	Shareholders Deficit
Balance at June 16, 1994		\$		\$	\$	\$	\$	\$	\$	\$
Issuance of common stock to founders for \$0.01 per share			1,785,725	18	17					35
Repurchase of common stock issued to founders			(189,733)	(2)	(63)					(65)
Issuance of Series A-E convertible preferred stock for \$1.96 to \$9.80 per share and \$4,003 in financing costs	9,669,539	74,960			(4,003)					(4,003)
Issuance of Series C and E convertible preferred stock warrants		12			(629)					(629)
Issuance of Series E convertible preferred stock and common stock for the acquisition of nura	1,733,914	14,070	18,498	1						1
Issuance of Series A-E convertible preferred stock upon exercise of warrants for \$3.43 to \$7.78 per share	39,625	226								
Repurchase of Series A convertible preferred stock	(51,021)	(100)								
Reclassification of preferred stock warrants to liabilities					(490)					(490)
Issuance of common stock upon exercise of common stock warrants			54,666	1	186					187
Issuance of common stock upon exercise of stock options for cash of \$0.35 to \$10.63 per share			1,192,423	12	759					771
Issuance of common stock for services at \$0.35 to \$0.52 per share			19,936		8					8
Early exercise of common stock subject to repurchase				(1)	(154)					(155)
Stock-based compensation			336		7,835		(12)	(239)		7,584
Repayment of note receivable from related party								239		239
Unrealized holding loss on available-for-sale securities						(4)				(4)
Net loss									(73,420)	(73,420)
Comprehensive loss										(73,424)

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Balance at December 31, 2007 (carried forward)	11,392,057	89,168	2,881,851	29	3,466	(4)	(12)	(73,420)	(69,941)
See notes to consolidated financial statements									

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**Table of Contents****OMEROS CORPORATION**

(A Development Stage Company)

**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND****SHAREHOLDERS EQUITY (DEFICIT) Continued**

(In thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional	Accumulated Other Comprehensive	Deferred	Deficit Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in Capital	Income (Loss)	Stock-Based Compensation	During the Development Stage	Shareholders Deficit
Balance at December 31, 2007 (brought forward)	11,392,057	\$ 89,168	2,881,851	\$ 29	\$ 3,466	\$ (4)	\$ (12)	\$ (73,420)	\$ (69,941)
Issuance of common stock upon exercise of stock options for cash of \$0.35 to \$2.45 per share			69,555	1	39				40
Issuance of common stock warrants in connection with notes payable					241				241
Vesting of early-exercised stock options					101				101
Stock-based compensation					2,303				2,303
Amortization of deferred stock-based compensation							12		12
Unrealized holding loss on available-for-sale securities for the year ended December 31, 2008						(95)			(95)
Net loss								(23,827)	(23,827)
Comprehensive loss									(23,922)
Balance at December 31, 2008	11,392,057	89,168	2,951,406	30	6,150	(99)		(97,247)	(91,166)
Issuance of Series E convertible preferred stock for cash of \$15.11 per share in connection with research and development funding agreement	122,451	1,851							
Issuance of common stock for \$10 per share upon completion of initial public offering, net of offering costs of \$6,388			6,820,000	68	61,744				61,812
Conversion of convertible preferred stock to common stock upon initial public offering	(11,514,508)	(91,019)	11,514,508	115	90,904				91,019
Conversion of preferred stock warrant liability to equity upon initial public offering					902				902
Issuance of common stock upon exercise of stock options for cash of \$0.98 to \$2.45 per share			25,633		28				28
Vesting of early-exercised stock options					5				5
Repurchase of early-exercised stock options			(25,970)						
Stock-based compensation					1,494				1,494
Unrealized holding gain on available-for-sale securities						140			140
Net loss								(21,089)	(21,089)
Comprehensive loss									(20,949)

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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)
Comprehensive loss						(29,292)

Balance at December 31, 2010	\$	21,920,836	\$	219	\$	167,838	\$		\$	(147,587)	\$	20,470
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See notes to consolidated financial statements

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**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(In thousands)**

	Year Ended December 31,			Period from June 16, 1994 (Inception) through December 31,
	2010	2009	2008	2010
<b>Operating activities</b>				
Net loss	\$ (29,251)	\$ (21,089)	\$ (23,827)	\$ (147,587)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	472	451	434	2,474
Stock-based compensation expense	2,178	1,494	2,315	13,830
Change in fair value of preferred stock warrant values and success fee liability		(848)	218	(253)
Non-cash interest expense	174	253	55	482
Loss on extinguishment of debt	296			296
Loss on sale of investment securities	33	34	76	112
Write-off of deferred public offering costs			1,948	1,948
Acquired in-process research and development				10,891
Other than temporary impairment loss on investments				163
Changes in operating assets and liabilities, net of nura acquisition in 2006:				
Grant and other receivables	(1,231)	(41)	(17)	(179)
Prepaid expenses and other current and noncurrent assets	(87)	42	19	(217)
Deferred public offering costs			(486)	(1,948)
Accounts payable and accrued expenses	1,462	207	(140)	6,327
Deferred revenue	11,452	470	(268)	10,854
<b>Net cash used in operating activities</b>	<b>(14,502)</b>	<b>(19,027)</b>	<b>(19,673)</b>	<b>(102,807)</b>
<b>Investing activities</b>				
Purchases of property and equipment	(807)	(279)	(164)	(2,879)
Purchase of Patobios intellectual property assets	(7,631)			(7,631)
Reimbursement of Patobios intellectual property assets	7,631			7,631
Purchases of investments	(57,765)	(64,207)		(205,869)
Proceeds from the sale of investments	78,173	11,045	5,572	121,889
Proceeds from the maturities of investments	323	1,039	5,158	45,026
Cash paid for acquisition of nura, net of cash acquired of \$87				(212)
<b>Net cash provided by (used in) investing activities</b>	<b>19,924</b>	<b>(52,402)</b>	<b>10,566</b>	<b>(42,045)</b>
<b>Financing activities</b>				
Proceeds from issuance of common stock upon initial public offering, net of offering costs of \$6,388		61,812		61,812
Proceeds from borrowings under note payable, net of loan origination costs and prepayment penalty	9,742		16,878	26,670
Payments on notes payable	(13,005)	(4,120)	(1,010)	(19,581)
Proceeds from issuance of common stock upon exercise of stock options	299	28	40	969

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Proceeds from the repayment of related party notes receivable				239
Proceeds from issuance of convertible preferred stock, net of issuance costs	1,851			78,234
Repurchase of unvested common stock and Series A convertible preferred stock	(48)			(213)
Net cash (used in) provided by financing activities	(2,964)	59,523	15,908	148,130
Net increase (decrease) in cash and cash equivalents	2,458	(11,906)	6,801	3,278
Cash and cash equivalents at beginning of period	820	12,726	5,925	
Cash and cash equivalents at end of period	\$ 3,278	\$ 820	\$ 12,726	\$ 3,278

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**Supplemental cash flow information**

Cash paid for interest	\$ 1,362	\$ 1,947	\$ 222	\$ 3,825
Issuance of common stock to Patobios in connection with purchase of intellectual property assets	\$ 3,146	\$	\$	\$ 3,146
Issuance of warrants	\$ 994	\$	\$ 241	\$ 1,235
Preferred stock and common stock issued in connection with nura acquisition	\$	\$	\$	\$ 14,070
Property acquired under capital lease	\$ 201	\$	\$	\$ 201

See notes to consolidated financial statements

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**OMEROS CORPORATION**

**(A Development Stage Company)**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1 Organization and Significant Accounting Policies**

*Organization*

We are a biopharmaceutical company committed to discovering, developing and commercializing products focused on inflammation, bleeding and disorders of the central nervous system. Our most clinically advanced product candidates are derived from our proprietary PharmacoSurgery platform designed to improve clinical outcomes of patients undergoing arthroscopic, ophthalmological, urological and other surgical and medical procedures. As substantially all of our efforts have been devoted to conducting research and development of our products, to developing our patent portfolio and to raising equity capital, we are considered to be in the development stage.

*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. The acquisition of nura was accounted for as a purchase of assets, and the results of nura have been included in our results since August 11, 2006.

*Initial Public Offering*

On October 13, 2009, we completed our initial public offering, or IPO, of 6,820,000 shares of our common stock at a price of \$10.00 per share. We received gross proceeds of \$68.2 million from this transaction, before underwriting discounts and commissions. In connection with the closing of our IPO, all of our shares of preferred stock outstanding at the time of the offering were automatically converted into 11,514,508 shares of common stock, and warrants to purchase up to 197,478 shares of Series E preferred stock were converted into warrants to purchase 197,478 shares of common stock.

*Financial Instruments and Concentrations of Credit Risk*

Cash and cash equivalents, receivables associated with grants, 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 funds, certificates of deposit, commercial paper and mortgage-backed securities issued by, or fully collateralized by, the U.S. government or U.S. government-sponsored entities.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

*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.

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Unrealized gains and losses are reported as a separate component of shareholders' deficit. Amortization, accretion, interest and dividends, realized gains and losses, and declines in value judged to be other-than-temporary are included in investment income. The cost of securities sold is based on the specific-identification method. Investments in securities with maturities of less than one year, or those for which management intends to use the investments to fund current operations, are included in current assets. We evaluate whether an investment is other-than-temporarily impaired. 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.

### *Deferred Public Offering Costs*

Deferred public offering costs represented primarily legal, accounting and other direct costs related to our IPO. Deferred public offering costs capitalized prior to 2009 of \$1.9 million were written-off to expense in 2008 due to a delay in the IPO. Costs of \$1.6 million, net of underwriting fees of \$4.8 million, were incurred in 2009 related to our IPO activities and were deferred until the completion of the IPO on October 13, 2009, at which time they were reclassified to additional paid-in capital as a reduction of the IPO proceeds.

### *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 five years. Leasehold improvements are stated at cost and amortized using the straight-line method over the shorter of the lease term or five 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.

### *Preferred Stock Warrant Liability*

Prior to the completion of the IPO, warrants to purchase our convertible preferred stock were classified as liabilities and were recorded at fair value. At each reporting period, any change in fair value of the freestanding warrants was recorded as other expense or income.

For the years ended December 31, 2009 and 2008, we recorded income (expense) of \$878,000 and \$(218,000), respectively, to reflect the change in the estimated fair value of the freestanding preferred stock warrants. The preferred stock warrant liability of \$902,000 was reclassified to equity upon the completion of our IPO in October 2009 with the conversion of all of the preferred stock warrants to common stock warrants.

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### *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 since inception relates to grant funding from third parties and revenue recognized in connection with funding from Vulcan Inc. and its affiliate, or Vulcan, and the Life Sciences Discovery Fund, or LSDF. We recognize such funds as revenue when the related qualified 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. Internal research and development costs are expensed as incurred. Internal and third-party research and development expenses are expensed as incurred.

### *In-Process Research and Development*

In connection with the acquisition of nura in August 2006, we recorded an expense of \$10.9 million for acquired in-process research and development. This amount represented the estimated fair value related to incomplete product candidate development projects for which, at the time of the acquisition, technological feasibility had not been established and there was no alternative future use.

### *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 necessary to reduce deferred tax assets to the amount expected to be realized.

### *Stock-Based Compensation*

We account for stock-based compensation under applicable accounting standards, which require that the measurement and recognition of compensation expenses for all share-based payments made to employees and directors be based on estimated fair values. We are using 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.

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For purposes of estimating the fair value of our common stock for stock options granted prior to the IPO, we estimated fair value of our common stock by performing a valuation analysis for each quarterly period during the six months ended June 30, 2009 and the year ended December 31, 2008. For the quarter ended September 30, 2009, we used the \$10.00 per share offering price from our IPO, which was completed on October 13, 2009. As a result, certain stock options granted during 2009 and 2008 had an exercise price different than the re-assessed estimated fair value of the common stock at the date of grant. We used these fair value estimates derived from our valuations to determine the stock compensation expense, which is recorded in our consolidated financial statements. The valuations were prepared using a methodology that first estimated our enterprise fair value as a whole, and then allocated a portion of the enterprise value to common stock. Subsequent to the IPO, we use the closing market price of our common stock on the grant date as the fair value of our common stock.

### *Segments*

We operate in only 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.

### *Adoption of Standards*

In 2009, the Financial Accounting Standards Board, or FASB, issued an Accounting Standards Update, or ASU, related to revenue recognition that amends the previous guidance on arrangements with multiple deliverables. This guidance provides principles and application guidance on whether multiple deliverables exist, how the arrangements should be separated, and how the consideration should be allocated. It also clarifies the method to allocate revenue in an arrangement using the estimated selling price. This guidance is effective for us January 1, 2011. The impact of the above guidance will be dependent on the terms and structure of revenue generating contracts negotiated in the future.

In January 2010, the FASB issued guidance that requires reporting entities to make new disclosures about recurring or nonrecurring fair-value measurements including significant transfers into and out of Level 1 and Level 2 fair value measurements and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair value measurements. The guidance is effective for annual reporting periods beginning after December 15, 2009, except for Level 3 reconciliation disclosures that are effective for annual periods beginning after December 15, 2010. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In 2010, the FASB issued an ASU related to revenue recognition that applies to arrangements with milestones relating to research or development deliverables. This guidance provides criteria that must be met to recognize consideration that is contingent upon achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This guidance is effective for us January 1, 2011. The impact of the above guidance will be dependent on the terms and structure of revenue generating contracts negotiated in the future.

### **Note 2 Net Loss Per Common Share**

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, less weighted-average unvested common shares subject to repurchase. Diluted net loss per common share is computed by dividing the net loss applicable to common shareholders 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 common share amounts for the years ended December 31, 2010, 2009 and 2008 were computed based on the shares of common stock outstanding during the respective periods. The net loss per share for the years ended December 31, 2010 includes the full effect of the 6,820,000 common shares issued in our IPO in the fourth quarter of 2009 and the conversion of our convertible preferred stock into

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11,514,508 shares of common stock upon completion of the offering. As a result of the issuance of these common shares during the fourth quarter of 2009, there is a lack of comparability in the basic and diluted net loss per share amounts for the period presented. The following table presents the computation of basic and diluted net loss per common share (in thousands, except share and per share data):

	Year Ended December 31,		
	2010	2009	2008
<b>Historical</b>			
<b>Numerator:</b>			
Net loss	\$ (29,251)	\$ (21,089)	\$ (23,827)
<b>Denominator:</b>			
Weighted-average common shares outstanding	21,420,883	7,233,109	2,937,789
Less: Weighted-average unvested common shares subject to repurchase		(14,194)	(54,267)
Denominator for basic and diluted net loss per common share	21,420,883	7,218,915	2,883,522
Basic and diluted net loss per common share	\$ (1.37)	\$ (2.92)	\$ (8.26)

Historical outstanding dilutive securities not included in diluted loss per common share calculation:

	Year Ended December 31,		
	2010	2009	2008
Convertible preferred stock			11,392,057
Outstanding options to purchase common stock	3,589,292	2,847,549	2,839,851
Warrants to purchase common stock and convertible preferred stock	609,016	209,017	234,230
Common stock subject to repurchase			28,762
Total	4,198,308	3,056,566	14,494,900

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

Cash, cash equivalents, restricted cash and short-term investments, all of which are carried at fair value, consisted of the following:

	December 31, 2010		
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses
		(in thousands)	
Cash and cash equivalents	\$ 3,471	\$	\$ 3,471
Money market funds	38,715		38,715
Mortgage-backed securities			
Total	\$ 42,186	\$	\$ 42,186
Amounts classified as cash and cash equivalents			\$ 3,278
Amounts classified as restricted cash			193
Amounts classified as short-term investments			38,715

Total	\$ 42,186
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	December 31, 2009			Fair Value
	Amortized Cost	Gross	Gross	
		Unrealized Gains	Unrealized Losses	
		(in thousands)		
Cash and cash equivalents	\$ 1,013	\$	\$	\$ 1,013
Money market funds	56,506			56,506
Mortgage-backed securities	2,938	41		2,979
Total	\$ 60,457	\$ 41	\$	\$ 60,498
Amounts classified as cash and cash equivalents				\$ 820
Amounts classified as restricted cash				193
Amounts classified as short-term investments				59,485
Total				\$ 60,498

As of December 31, 2009, our investment portfolio was made up of cash and cash equivalents and mortgage-backed, adjustable-rate securities issued by, or fully collateralized by, the U.S. government or U.S. government-sponsored entities. In May 2010 we sold the mortgage-backed securities and invested the proceeds in cash and cash-equivalent funds and mutual funds invested in highly liquid securities. All investments are classified as short-term and available-for-sale on the accompanying balance sheets.

To determine the fair market value of our mortgage-backed securities, our external investment manager formally prices securities at least monthly with external market sources. The external sources have historically been primary and secondary broker/dealers that trade and make markets in an open market exchange of these securities. Mortgage-backed securities are priced using round lot non-binding pricing from a single external market source for each of the investment classes within our portfolio. We have used this non-binding pricing information to estimate fair market value and do not make adjustments to these quotes unless a review indicates an adjustment is warranted. To determine pricing, the external market sources use inputs other than quoted prices in active markets that are either directly or indirectly observable such as trading activity that is observable in these securities or similar or like-kind securities, rate reset margins, reset indices, pool diversification and prepayment levels. In addition, in evaluating if this pricing information should be adjusted, the prices obtained from these external market sources are compared against independent pricing services.

The composition of our investment income is as follows:

	Year Ended December 31,		
	2010	2009 (in thousands)	2008
Gross interest income	\$ 200	\$ 249	\$ 737
Gross realized gains on investments	3	7	16
Gross realized losses on investments	(36)	(42)	(92)
Total investment income	\$ 167	\$ 214	\$ 661

Realized gains and losses on sales of investments are calculated based on the specific identification method and related primarily to the sale of mortgage-backed securities.

**Table of Contents****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 established 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:

These levels include:

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 the Company, which reflect those that a market participant would use.

In May 2010, we sold our remaining mortgage-backed securities and invested the proceeds in cash and cash-equivalent funds and mutual funds invested in highly liquid securities. This resulted in a sale of the \$3.0 million in Level 2 investments as of December 31, 2009 and a subsequent purchase of Level 1 investments. 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, 2010		
		Level 2	Level 3	Total
		(in thousands)		
Assets:				
Money market funds classified as cash equivalents	\$ 2,323	\$	\$	\$ 2,323
Money market funds classified as short term investments	38,715			38,715
Total	\$ 41,038	\$	\$	\$ 41,038

	Level 1	December 31, 2009 Level 2      Level 3 (in thousands)		Total
Assets:				
Money market funds	\$ 57,073	\$	\$	\$ 57,073
Mortgage-backed securities		2,979		2,979
Total	\$ 57,073	\$ 2,979	\$	\$ 60,052

Cash of \$1,148,000 and \$446,000 is excluded in our fair-value hierarchy disclosure as of December 31, 2010 and 2009, respectively. Additionally, the fair-value hierarchy disclosure includes restricted cash of \$193,000 as of December 31, 2010 and 2009. The changes in fair value of our short-term investments are included in accumulated comprehensive income (loss) in the accompanying balance sheets. For the year ended December 31, 2010 there were no unrealized gains or (losses) and for the year ended December 31, 2009 there were unrealized gains and (losses) of \$41,000 and \$0, respectively. Unrealized gains (losses) are associated with our short-term investments and are included in accumulated comprehensive income in the accompanying balance sheets.

Prior to their conversion to common stock warrants, the change in fair value of our preferred stock warrant liability and notes payable success fee liability was recorded as other income (expense) in the consolidated statements of operations. For the years ended December 31, 2009 and 2008 we recorded other income (expense) of \$848,000 and \$(209,000) related to the aggregate change in fair value of the preferred stock warrant liability and notes payable success fee liability. See Note 10 for a discussion of the valuation methodology used to estimate the fair value of the preferred stock warrant liability and the reclassification to additional paid-in-capital upon conversion of the preferred stock warrants to common stock warrants in connection with the IPO.



**Table of Contents****Note 5 Certain Balance Sheet Accounts***Grant and Other Receivables*

Grant and other receivables consisted of the following:

	December 31, 2010	2009
	(in thousands)	
Grant funding receivable	\$ 1,144	\$ 143
Other receivables	335	105
Grant and other receivables	\$ 1,479	\$ 248

On October 29, 2010, we were awarded grants totaling approximately \$1.7 million from the U.S. government pursuant to the Qualifying Therapeutic Discovery Project Program. We received approximately \$1.5 million in 2010, which was recorded as other income. The remaining \$236,000 is included in other receivables and expected to be received during the first quarter of 2011.

*Property and Equipment*

Property and equipment consisted of the following:

	December 31, 2010	2009
	(in thousands)	
Computer equipment	\$ 518	\$ 279
Computer software	414	379
Office equipment and furniture	284	284
Leasehold improvements	310	278
Capital lease equipment	201	
Laboratory equipment	1,978	1,503
Total	3,705	2,723
Less accumulated depreciation and amortization	(2,083)	(1,637)
Property and equipment, net	\$ 1,622	\$ 1,086

Our property and equipment have lives that range from three to five years with the exception of the leasehold improvements that are limited to the lesser of the term of the lease or five years. Depreciation expense for the years ended December 31, 2010, 2009 and 2008 was \$472,000, \$392,000 and \$330,000 respectively.

*Accrued Expenses*

Accrued expenses consisted of the following:

	December 31, 2010	2009
	(in thousands)	
Clinical trials	\$ 2,548	\$ 1,868

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Employee compensation	974	324
Contract preclinical research	157	60
Other accruals	1,388	585
Accrued expenses	\$ 5,067	\$ 2,837

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**Table of Contents***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 were no unrealized gains (losses) as of December 31, 2010 as we sold the underlying available-for-sale securities in May 2010. The components of comprehensive loss are as follows:

	Year Ended December 31,		
	2010	2009	2008
	(in thousands)		
Net loss	\$ (29,251)	\$ (21,089)	\$ (23,827)
Unrealized gain (loss) on available-for-sale securities	(41)	140	(95)
Comprehensive loss	\$ (29,292)	\$ (20,949)	\$ (23,922)

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

In October 2010, we entered into a loan and security agreement with Oxford Finance Corporation, or Oxford, pursuant to which Oxford has agreed to lend us up to \$20.0 million in two tranches of \$10.0 million each. Upon signing the agreement, we borrowed the first tranche of \$10 million, or Tranche 1, approximately \$9.0 million of which we used to repay all outstanding amounts, including a 1.0% prepayment fee, due under our loan and security agreement with BlueCrest Venture Finance Master Fund Limited, or BlueCrest. Upon payment of the approximately \$9.0 million to BlueCrest, all of our liabilities to BlueCrest were paid in full, and all commitments of BlueCrest to us under the loan agreement were terminated. In connection with the repayment of the BlueCrest liability, we recognized as interest expense \$208,000 of unamortized debt issuance costs and debt discount. Prior to the refinancing, we recognized non-cash interest expense associated with amortization of these deferred costs of \$166,000 and \$253,000 for the years ended December 31, 2010 and 2009, respectively.

Under the terms of our loan and security agreement with Oxford, at any time before March 31, 2011 we may, at our sole option, borrow from Oxford the second tranche of \$10.0 million, or Tranche 2, subject to our satisfaction of specified conditions precedent described in the agreement. We may use the proceeds remaining from Tranche 1 and, if borrowed, Tranche 2, for working capital and general business purposes. Interest on Tranche 1 accrues at an annual fixed rate of 8.55% and, if borrowed, interest on Tranche 2 will accrue at an annual fixed rate equal to the 3-month LIBOR rate in effect immediately prior to the funding of Tranche 2 plus 8.25%. Payments due under Tranche 1 and, if borrowed, Tranche 2, are interest only, payable monthly, in arrears, through October 31, 2011. Beginning November 1, 2011, 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, October 21, 2014. We may prepay all, but not less than all, of the outstanding principal and accrued and unpaid interest under the Oxford loan agreement at any time upon prior notice to Oxford and the payment of a fee equal to 1% of the then-outstanding principal amount. As security for our obligations under the Oxford agreement, we granted Oxford a security interest in substantially all of our assets, excluding intellectual property.

Upon the last payment date of the amounts borrowed from Oxford, we will be required to pay Oxford a final payment fee equal to 5.0% of Tranche 1 (\$500,000) and, if borrowed, 5.0% of Tranche 2, provided that the percentage for Tranche 2 will decrease by 0.20% for each month that lapses between the date of the Oxford agreement and the funding date for Tranche 2. The final payment fee for Tranche 1 was recorded as a discount to the note and is being amortized to interest expense using the effective interest method over the repayment term of the initial loan amount. Non-cash interest expense associated with amortization of the debt discount totaled \$31,000 for the year ended December 31, 2010.

In connection with the loan and security agreement, we incurred debt issuance costs of \$169,000 that were capitalized and included in other assets in the December 31, 2010 balance sheet. Included in the debt issuance costs is a one-time facility fee payment to Oxford of \$50,000 for Tranche 1. The debt issuance costs are being

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amortized to interest expense using the effective interest method over the term of the initial loan amount. Non-cash interest expense associated with amortization of the debt issuance costs totaled \$10,000 for the year ended December 31, 2010. The remaining unamortized balance is \$159,000 at December 31, 2010.

The Oxford agreement contains customary affirmative and negative covenants, including covenants that limit or restrict Omeros' 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, repurchase stock, in each case subject to customary exceptions for a credit facility of this size and type. The Oxford agreement contains no cash covenant.

The Oxford agreement includes customary events of default that include, among other things, non-payment defaults, inaccuracy of representations and warranties, covenant defaults, material adverse change default, cross default to material indebtedness, bankruptcy and insolvency defaults, material judgment defaults, and a change of control default. The occurrence of an event of default could result in the acceleration of the obligations under the Oxford agreement. Under certain circumstances, a default interest rate will apply on all obligations during the existence of an event of default under the Oxford agreement at a per annum rate equal to 5% above the otherwise applicable interest rate.

Material adverse effect, or 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, 2010.

*Software Financing Arrangement*

In December 2008, we entered into agreements to finance certain software licenses. The amount financed totaled \$193,000 and is payable over a three-year period with an effective interest rate of 8.0%.

*Equipment Financing*

During 2010, we entered into a lease agreement for the lease of copier equipment. The lease has been treated as a capital lease with an original principal amount totaling \$201,000 and a lease term of 60 months with an effective interest rate of 8.51%. The equipment related to this capital lease is included in our property, plant and equipment. At December 31, 2010, this equipment had a net book value of \$184,000 which included \$17,000 of accumulated depreciation.

*Future Principal Payments*

Future principal payments as of December 31, 2010 under the loan and security agreement, capital lease agreement and the software financing arrangement based on stated contractual maturities are as follows (in thousands):

<b>Year Ending December 31,</b>	<b>Total</b>
2011	592
2012	3,134
2013	3,414
2014	3,085
2015	33
Total principal payments	10,258
Less current portion	(592)
Total notes payable, net of current portion	\$ 9,666



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The unamortized debt discount is \$469,000 and \$315,000 at December 31, 2010 and 2009, respectively.

### **Note 7 Revenue**

We have received Small Business Innovative Research, or SBIR, grants from the National Institutes of Health since inception totaling \$4.1 million through December 31, 2010. The purpose of the grants is to support research and development of our product candidates. For the years ended December 31, 2010, 2009 and 2008, we recorded revenue related to these grants of \$876,000, \$432,000 and \$670,000, respectively. As of December 31, 2010, \$688,000 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 PDE10 inhibitor product candidate for the treatment of schizophrenia. The funding is expected to advance our PDE10 program through the completion of Phase 1 clinical trials. Under the agreement, we may receive grant and equity funding of up to \$9.0 million upon achievement of research milestones. We hold the exclusive rights to the technology. In consideration for SMRI's grant funding, we may 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 candidate does not reach commercialization, we are not required to repay the grant funds. Through December 31, 2010, we have received from SMRI a total of \$5.7 million. As of December 31, 2010, amounts included in the accompanying balance sheet pertaining to this agreement included \$227,000 in deferred revenue. In addition, in 2007 and 2009 we sold 255,103 shares of Series E convertible preferred stock for \$3.2 million, which was subsequently converted to common stock. For the years ended December 31, 2010, 2009 and 2008, we recognized revenue under this agreement of \$475,000, \$548,000 and \$500,000, respectively.

In November 2008, we entered into an agreement with The Michael J. Fox Foundation, or MJFF, to provide funding for a study of PDE7 inhibitors for the treatment of Parkinson's disease. The agreement was for a one-year period and provided funding of actual costs incurred up to a total of \$464,000. In consideration of MJFF's grant funding, MJFF will receive access to the study data results, subject to certain restrictions on data sharing. We hold and will continue to hold the exclusive rights to the technology and have no future obligation to MJFF for royalties or other monetary consideration resulting from the ongoing development of the technology. We have received total payments from MJFF of \$464,000, which consist of an advance payment of \$232,000 received in December 2008 and a second advance payment of \$232,000 received in July 2009. The payments were initially recorded as deferred revenue. As of December 31, 2009 all \$464,000 of funds had been recognized as revenue as the related expenses were incurred. No revenue was recognized under this agreement prior to 2009.

In May 2010, we entered into a second agreement with MJFF to provide funding for a study of PDE7 inhibitors for the treatment of Parkinson's disease. The agreement is for a six-month period and provides funding of actual costs incurred up to a total of \$76,000. In consideration of MJFF's grant funding, MJFF will receive access to the study data results, subject to certain restrictions on data sharing. We hold and will continue to hold the exclusive rights to the technology and have no future obligation to MJFF for royalties or other monetary consideration resulting from the ongoing development of the technology. The funds are being recognized as grant revenue as the related expenses have been incurred. For the year ended December 31, 2010, we recognized grant revenue of \$74,000.

In October 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. 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, \$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 grant revenue or as a reduction of 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 the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or

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LSDF, under which we received a \$5.0 million grant award from LSDF that will be paid to us as reimbursement of expenses that we incur or equipment that we purchase for our GPCR program. For the year ended December 31, 2010, we have recorded reductions to the Vulcan deferred revenue balance of \$484,000, which includes \$468,000 recognized as revenue and \$16,000 recorded as costs reductions to assets. As of December 31, 2010, amounts included in the accompanying balance sheet pertaining to the Vulcan agreement included \$7.7 million in deferred revenue. For the year ended December 31, 2010, we recognized revenue of \$212,000 and reduced the cost basis of assets of \$494,000 under the LSDF agreement. See additional discussion of the Vulcan and LSDF agreements under Note 9.

**Note 8 Acquisition of nura**

Effective August 11, 2006, we acquired nura, inc., or nura, a private biotechnology company which expanded and diversified our potential product pipeline and strengthened our discovery capabilities. We completed the acquisition of nura through the issuance of 1,733,914 shares of our Series E convertible preferred stock and 18,498 shares of common stock, and the assumption of a \$2.4 million promissory note. Total consideration was valued at \$14.4 million. The convertible preferred stock issued in conjunction with the acquisition included shares issued to certain nura shareholders in exchange for their \$5.2 million investment in the Company concurrent with the acquisition. nura's primary assets included its research and development team and PDE10 preclinical product candidates.

The acquisition of nura, a development stage drug discovery company, was accounted for as an acquisition of assets rather than as a business. The purchase price included \$10.9 million associated with acquired research and development which was immediately recognized as research and development expense in 2006.

**Note 9 Commitments and Contingencies**

We lease laboratory and corporate office space and rent equipment under operating lease agreements that include certain rent escalation terms. The laboratory space lease term extends through September 30, 2012 and the lease term for the corporate office space expires July 31, 2014. Rental of equipment extends into 2012. We sublease a portion of our leased properties. Future minimum payments related to the leases, which exclude common area maintenance and related operating expenses, at December 31, 2010, are as follows:

Year Ending December 31,	Lease Payments	Sublease Income (in thousands)	Net Lease Payments
2011	1,568		1,568
2012	1,282		1,282
2013	408		408
2014	238		238
Total	\$ 3,496	\$	\$ 3,496

Rent expense totaled \$2.1 million, \$2.3 million and \$2.0 million for the years ended December 31, 2010, 2009 and 2008, respectively. Rental income received under noncancelable subleases was \$793,000, \$799,000 and \$587,000 for the years ended December 31, 2010, 2009 and 2008, respectively. Rental income is recorded as other income in the consolidated statements of operations.

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, 2010, the maximum amount of royalties payable by us is \$12.8 million. We have not paid any such royalties through December 31, 2010.

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In July 2008, we entered into a discovery and development agreement with Affitech AS, or Affitech, to isolate and optimize fully human antibodies for our mannan-associated serine protease-2, or MASP-2, program. Under the terms of the agreement, Affitech will apply its human antibody libraries and proprietary antibody discovery and screening technologies to generate fully human MASP-2 antibodies for us. In March 2010, we amended the antibody development agreement. Under the terms of the amendment, Affitech released us from any future obligations to make royalty or milestone payments in exchange for \$500,000. The agreement also stipulates certain optional services that may be requested by us for a fee. The agreement may be terminated for cause by either party, or at any time by us by providing 30 days advance written notice to Affitech. We recorded research and development expense under the agreement totaling \$500,000, \$0, and \$400,000 in 2010, 2009 and 2008, respectively.

In October 2008, we entered into an antibody development agreement with North Coast Biologics LLC, or North Coast, to isolate and optimize antibodies for our MASP-2 program. Under the terms of the agreement, North Coast will apply its proprietary antibody discovery and screening technologies to generate MASP-2 antibodies for us. We recorded research and development expenses under the agreement totaling \$150,000 in 2008. No expense has been incurred for the years ended December 31, 2010 and 2009. Under the agreement, we may be required to make additional payments to North Coast of up to \$4.0 million upon the achievement of certain development events, such as initiation of clinical trials and the receipt of marketing approval for a drug product containing an antibody developed by North Coast. The agreement also provides us with an option to have North Coast generate antibodies for additional targets. If this option is exercised, we may be required to make additional payments to North Coast for rights to the technology and milestone payments of up to \$4.1 million per selected target. In addition, we are obligated to pay North Coast a low single-digit percentage royalty on any of our net sales of drug products containing an antibody developed by North Coast under the agreement. The agreement may be terminated for cause by either party.

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 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 2010, we amended the patent assignment agreement to include all intellectual property rights, including patent applications, related to nutraceuticals that increase PPAR $\gamma$  activity. Under the amended agreement, we may be required to make payments of up to \$3.8 million in total, for both PPAR $\gamma$  agonists and nutraceuticals 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.

On March 3, 2010, we entered into a license agreement with Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.), or Daiichi, pursuant to which we received an exclusive license to PDE7 inhibitors claimed in certain patents and pending patent applications owned by Daiichi for use in the treatment of movement disorders and other specified indications. Under the agreement, we agreed to make milestone payments to Daiichi of up to \$23.5 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 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 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.

On April 23, 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 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

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of any disease or condition. Upon execution of the agreement, we made a one-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 MASP-2 inhibitor product that is covered by the patents licensed by us under the agreement.

In September 2008, we entered into a technology option agreement with Patobios Limited, or Patobios, to evaluate and potentially acquire the intellectual property rights covering Patobios' G protein-coupled receptor, or GPCR, technology. Under the terms of the agreement, as amended in November 2009, Patobios granted us an option to evaluate the technology over four option periods commencing September 2008 and continuing until December 2010. We made a non-refundable payment of \$200,000 CAD (\$188,000 USD) to Patobios following execution of the agreement for the first nine-month option period and a payment of \$522,000 CAD (\$471,000 USD) for the second six-month option period, all of which was charged to research and development expense. As of December 31, 2009, the second option period was automatically extended until January 2010 at a cost to us of \$108,000 CAD (\$104,000 USD) and we exercised our right to extend the third option period from January 2010 to June 2010 at a cost to us of \$542,000 CAD (\$516,000 USD), which was recorded as expense in 2009. In June 2010, we exercised our right to extend the fourth option period from July 2010 to December 2010 at a cost to us of \$500,000 CAD (\$487,000 USD). Under the terms of the agreement, we had the exclusive option to acquire the intellectual property rights, including patents, covering Patobios' GPCR technology at any time during any of the option periods. In October 2010 we gave notice to Patobios of our intent to exercise our right to purchase Patobios' GPCR technology. In November 2010, we completed the acquisition from Patobios of intellectual property assets related to an assay technology for use in our GPCR program. The purchase price of these assets was \$10.8 million CAD, of which we paid \$7.8 million CAD (\$7.6 million USD) in cash and the remaining \$3.0 million CAD (\$3.2 million USD) in the form of 379,039 shares of our common stock. As Vulcan funded the purchase of these assets, we have no cost basis in the assets acquired.

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 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. After we have received approximately \$1.5 billion of cumulative net proceeds, 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 LSI, to be established pursuant to LSDF agreement. The LSI will be a non-profit, tax-exempt organization with a mission to advance life sciences in the State of Washington.

As discussed above, 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 exercisable for 133,333 shares, with exercise prices of \$20, \$30 and \$40 per share, respectively. The warrants may be exercised for cash or on a cashless basis through the surrender at the time of exercise of a number of shares that would otherwise be issuable equal to the fair market value of our common stock at the time of exercise. 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 shall be junior to any existing or future security interests granted in connection with a financing transaction and which shall 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.

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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. In addition, pursuant to our agreements with Vulcan and LSDF, we have agreed (1) to use commercially reasonable efforts to screen at least 75% of the currently known human Class A orphan GPCRs within the next 19 months, subject to possible extensions and (2) to commence a medicinal chemistry effort focused on developing a product candidate with respect to one orphan GPCR for which compounds were identified using the GPCR assay technology.

### **Note 10 Warrants**

On October 21, 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 warrants may be exercised for cash or on a cashless basis through the surrender at the time of exercise of a number of shares that would otherwise be issuable equal to the fair market value of our common stock at the time of exercise and 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 August 24, 2009, in connection with the IPO, we waived a termination clause included in certain outstanding warrants to purchase up to 197,478 shares of Series E convertible preferred stock at an exercise price of \$12.25 per share that would have caused these warrants to terminate upon completion of the IPO if not previously exercised. The warrants were originally issued in 2007 as compensation for assistance with our Series E convertible preferred stock financing. The holders of these warrants included members of the IPO selling group and related persons, among other persons. As a result of this waiver, the warrants remain outstanding following completion of the IPO and will terminate upon the earlier of (a) a change of control as defined in the warrants and (b) March 29, 2012. We revalued the warrants based on the fair value as of the closing of the IPO when the warrants converted to common stock warrants, which resulted in an adjustment to the preferred stock warrant liability. The related income, was included in other income, net. The balance of the preferred stock warrant liability was reclassified to additional paid-in-capital upon the conversion of the preferred stock warrants to common stock warrants. The common stock warrants are recorded in permanent equity and are not adjusted to fair value on a recurring basis. As of December 31, 2010 and 2009 we had 609,016 and 209,017 common stock warrants outstanding with a weighted average exercise prices of \$23.85 and \$12.08, respectively.

Until the completion of our IPO, the fair value of the preferred stock warrants was classified as a liability on the Consolidated Balance Sheet and was adjusted to fair value using the Black-Scholes option pricing model at the end of each reporting period. The remaining preferred stock warrant liability was reclassified to additional paid-in-capital upon conversion of the preferred stock warrants to common stock warrants in connection with the IPO that was completed on October 13, 2009. The increase in the fair value of the preferred stock warrants totaled \$(878,000) and \$218,000 for the years ended December 31, 2009 and 2008, respectively, and is included in other income, net.

### **Note 11 Shareholders' Equity**

#### *Preferred Stock*

In connection with the closing of the IPO in 2009, all of our shares of preferred stock outstanding at the time of the offering were automatically converted into 11,514,508 shares of common stock.

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On February 18, 2009, we received \$3.1 million in connection with the funding agreement with SMRI. Under the terms of the agreement, we issued 122,449 shares of Series E convertible preferred stock. The estimated fair value of these shares was \$1.9 million, or \$15.11 per share. We recorded \$1.9 million of the proceeds as equity and the remaining as deferred revenue.

As discussed in Note 8, effective August 11, 2006, we acquired nura and issued 1,733,914 shares of Series E convertible preferred stock and 18,498 shares of common stock. Concurrently, certain nura stockholders purchased 530,614 shares of our Series E convertible preferred stock for \$5.2 million.

*Common Stock*

In July 2010, we entered into an equity line financing facility with Azimuth Opportunity, Ltd., or Azimuth, pursuant to which we may sell up to \$40.0 million of our shares of common stock over a 24-month term. From time to time over the 24-month term, and in our sole discretion, we may 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 4.00% to 7.00%, based on a minimum price that we solely specify. In addition, in our sole discretion, but subject to certain limitations, we may require Azimuth to purchase a percentage of the daily trading volume of our common stock for each trading day during the draw down period. 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 4,297,495 shares in connection with the committed equity line financing facility.

In partial consideration for Azimuth's execution and delivery of the equity line financing facility agreement, we paid to Azimuth \$100,000 in cash. We also paid \$35,000 of Azimuth's legal fees and expenses. All costs were charged to general and administrative expense as incurred. No additional legal fees incurred by Azimuth are payable by us in connection with any sale of shares to Azimuth. In connection with this facility, we also entered into a placement agent agreement with Reedland Capital Partners, or Reedland. We have agreed to pay Reedland, upon each sale of our common stock to Azimuth, a fee equal to 0.5% of the aggregate dollar amount of common stock purchased by Azimuth upon settlement of each such sale.

As of December 31, 2010, we had reserved shares of common stock for the following purposes:

Options granted and outstanding	3,589,292
Options available for future grant	1,079,572
Common stock warrants	609,016
Total shares reserved	5,277,880

**Note 12 Stock-Based Compensation***Stock Options*

In 2008, our board of directors adopted and shareholders approved the 2008 Equity Incentive Plan, or 2008 Plan. The 2008 Plan provides for the grant of incentive and nonstatutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, directors and consultants and subsidiary corporations' employees and consultants. 892,857 shares of common stock were initially reserved for issuance under the 2008 Plan. 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

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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, 2010 and 2009, a total of 357,135 and 321,528 shares, respectively, 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, 2011 and January 1, 2010, in accordance with the 2008 Plan annual increase provisions, the authorized shares in the 2008 Plan increased by 1,096,041 and 1,064,279, respectively.

Under the 1998 Plan, 4,240,569 shares of common stock were reserved for the issuance of incentive and nonqualified stock options to any former, current, or future employees, officers, directors, agents, or consultants, including members of technical advisory boards and any of our independent contractors. Options are granted with exercise prices equal to the fair value of the common stock on the date of the grant, as determined by our board of directors. The terms of options may not exceed ten years. Generally, options vest over a four-year period.

Prior to 2005, our board of directors approved the grant of options to purchase 75,971 shares of our common stock outside of the 1998 Plan. These options were granted with exercise prices equal to the fair value of the common stock on the date of grant, as determined by the board of directors.

In connection with our acquisition of nura on August 11, 2006, we assumed all of the outstanding options issued under nura's 2003 Stock Plan, or the nura Plan. As of December 31, 2010 and 2009, options to purchase 2,981 shares of our common stock were outstanding under the nura Plan and no shares remained available for future issuance pursuant to the nura Plan. These options were granted with exercise prices equal to the fair value of nura's common stock on the date of grant, as determined by nura's board of directors. We do not intend to issue any additional stock options pursuant to the nura Plan.

A summary of stock option activity and related information follows:

	Shares Available for Grant	Options Outstanding	Weighted- Average Exercise Price per Share	Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2009	1,013,256	2,847,549	\$ 1.94		
Authorized increase in 2008 Plan shares	1,099,886				
Expired	(35,607)		1.31		
Granted	(1,174,585)	1,174,585	6.39		
Exercised		(256,220)	1.17		
Cancelled	176,622	(176,622)	9.41		
Balance at December 31, 2010	1,079,572	3,589,292	\$ 3.09	7.09	\$ 18,602
Vested and expected to vest at December 31, 2010		3,464,458	\$ 2.96	7.01	\$ 18,391
Exercisable at December 31, 2010		2,483,941	\$ 1.66	6.18	\$ 16,405



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Information about stock options outstanding and exercisable is as follows:

Range of Exercise Price	December 31, 2010			Options Exercisable	
	Options Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Exercise Price
Number of Options				Number of Options	
\$0.52-0.78	31,786	1.04	\$ 0.53	31,786	\$ 0.53
\$0.98	1,880,060	5.89	0.98	1,880,060	0.98
\$1.96-6.05	1,028,604	8.12	4.49	442,318	3.02
\$6.30-13.49	648,842	9.23	7.09	129,777	7.07
\$0.52-13.49	3,589,292	7.09	\$ 3.09	2,483,941	\$ 1.66

At December 31, 2010 there were 1,105,351 unvested options outstanding that will vest over a weighted-average period of 2.9 years. Excluding non-employee stock options, the total estimated compensation expense of these shares is up to \$4.5 million.

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 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:

	2010	December 31, 2009	2008
Estimated weighted-average fair value	\$4.34	\$7.47	\$9.27
<b>Weighted-Average Assumptions</b>			
Expected volatility	73%-77%	71%-78%	60%
Expected term (in years)	6.08	6.08	6.08
Risk-free interest rate	1.72%-2.77%	2.13%-2.72%	2.8%-3.40%
Expected dividend yield	0%	0%	0%

*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.

*Expected Term.* We elected to utilize the simplified method for plain vanilla options to value 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.

*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.

*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.



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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, 2010, 2009 and 2008, 9,600, 0 and 0 options were granted to non-employees, respectively.

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

	Year Ended December 31,		
	2010	2009	2008
	(in thousands)		
Research and development	\$ 971	\$ 879	\$ 983
General and administrative	1,207	615	1,332
<b>Total</b>	<b>\$ 2,178</b>	<b>\$ 1,494</b>	<b>\$ 2,315</b>

In connection with the non-employee options, we recognized expense of \$139,000, \$31,000 and \$234,000 during the years ended December 31, 2010, 2009 and 2008, respectively.

**Note 13 Income Taxes**

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

Significant components of deferred tax assets are as follows:

	December 31,	
	2010	2009
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 39,820	\$ 30,925
Deferred revenue	91	239
Stock-based compensation	991	130
Research and development tax credits	3,192	2,634
Investment in Partnership	604	
Other	388	117
	45,086	34,045
Less valuation allowance	(45,086)	(34,045)
Net deferred tax assets	\$	\$

As of December 31, 2010 and 2009, we had net operating loss carryforwards of approximately \$117.1 million and \$90.9 million, respectively, and research and development tax credit carryforwards of approximately \$3.2 million and \$2.6 million, respectively. Unless previously utilized, our net operating loss and research and development tax credit carryforwards will expire between 2011 and 2030. The difference between the net operating loss carryforwards and the net loss for financial reporting purposes relates primarily to in-process research and development, accrued vacation, depreciation and stock-based compensation. The Vulcan funding arrangement is treated as a partnership for income tax purposes.



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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 (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 \$1.3 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 \$11.1 million, \$6.8 million and \$7.2 million in 2010, 2009 and 2008, respectively, primarily due to net operating losses incurred during these periods.

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

	2010	December 31, 2009 (in thousands)	2008
Statutory tax rate	(34)%	(34)%	(34)%
Permanent difference	(1)	4	6
Change in valuation allowance	27	20	21
Other	8	10	7
Effective tax rate			

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

The guidance for accounting for uncertainties in income taxes requires that we recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As 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. The amount of the reduction as of December 31, 2007 was \$227,000 and there was no change in 2008, 2009, and 2010. 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 14 Related-Party Transactions**

We conduct research using the services of one of our founders, Pamela Pierce Palmer, M.D., Ph.D. Costs incurred for the years ended December 31, 2010, 2009 and 2008 totaled \$5,000 per year, and \$455,000 for the period of inception (June 16, 1994) through December 31, 2010. In 2007, we granted Dr. Palmer an option to purchase 20,408 shares of common stock and recognized \$51,000, \$(15,000) and \$57,000 of non-cash compensation associated with this option for the years ended December 31, 2010, 2009 and 2008, respectively, and \$136,000 for the period of inception (June 16, 1994) through December 31, 2010.

**Table of Contents****Note 15 401(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 16 Quarterly Information (Unaudited)**

The following table summarizes the unaudited statements of operations for each quarter of 2010 and 2009 (in thousands except per share amounts):

	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
			<b>2010</b>	
Revenue	\$ 378	\$ 497	\$ 254	\$ 976
Total operating expenses	6,803	8,131	7,744	9,533
Loss from operations	(6,425)	(7,634)	(7,490)	(8,557)
Net loss	(6,661)	(7,804)	(7,555)	(7,231)
Basic and diluted net loss per share	\$ (0.31)	\$ (0.36)	\$ (0.35)	\$ (0.34)
			<b>2009</b>	
Revenue	\$ 197	\$ 371	\$ 442	\$ 434
Total operating expenses	5,432	6,052	4,969	5,749
Loss from operations	(5,235)	(5,681)	(4,527)	(5,315)
Net loss	(5,482)	(6,109)	(3,916)	(5,582)
Basic and diluted net loss per share	\$ (1.87)	\$ (2.09)	\$ (1.34)	\$ (0.28)

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit</b>	<b>Footnote</b>	<b>Description</b>
<b>Number</b>	<b>Reference</b>	
2.1	(1)	Agreement and Plan of Reorganization among Omeros Corporation, Epsilon Acquisition Corporation, nura, inc. and ARCH Venture Corporation dated August 4, 2006
3.1	(2)	Amended and Restated Articles of Incorporation of Omeros Corporation
3.2	(2)	Amended and Restated Bylaws of Omeros Corporation
4.1	(3)	Form of Omeros Corporation common stock certificate
4.2	(1)	Stock Purchase Warrant issued by nura, inc. to Oxford Finance Corporation dated April 26, 2005 (assumed by Omeros Corporation on August 11, 2006)
4.3	(1)	Amended and Restated Investors Rights Agreement among Omeros Corporation and holders of capital stock dated October 15, 2004
4.4	(4)	Form of Omeros Corporation Stock Purchase Warrant (as of December 31, 2010, warrants in this form permitted the purchase up to a total of 167,885 shares of common stock)
4.5	(4)	Form of Omeros Corporation Stock Purchase Warrant (as of December 31, 2010, warrants in this form permitted the purchase up to a total of 29,593 shares of common stock)
4.6	(4)	Form of Notice of Waiver of Warrant Termination (applicable to Stock Purchase Warrants filed as Exhibits 4.4 and 4.5)
4.7	(5)	Registration Rights Agreement dated July 28, 2010 between Omeros Corporation and Azimuth Opportunity, Ltd.
4.8	(6)	Form of Common Stock Warrant issued by Omeros Corporation to Cougar Investment Holdings LLC, which warrants were subsequently assigned to its affiliate Vulcan Capital Venture Capital II LLC (as of December 31, 2010, warrants in this form permitted the purchase of up to a total of 399,999 shares of common stock)
10.1	(1)*	Form of Indemnification Agreement entered into between Omeros Corporation and its directors and officers
10.2	(1)*	Second Amended and Restated 1998 Stock Option Plan
10.3	(1)*	Form of Stock Option Agreement under the Second Amended and Restated 1998 Stock Option Plan
10.4	(1)*	nura, inc. 2003 Stock Plan
10.5	(1)*	Form of Stock Option Agreement under the nura, inc. 2003 Stock Plan
10.6	(7)*	2008 Equity Incentive Plan
10.7	(7)*	Form of Stock Option Award Agreement under the 2008 Equity Incentive Plan (used for option awards granted after October 7, 2009)
10.8	(7)*	Form of Stock Option Award Agreement under the 2008 Equity Incentive Plan (used for option awards granted on or before October 7, 2009)
10.9	(8)*	Second Amended and Restated Employment Agreement between Omeros Corporation and Gregory A. Demopoulos, M.D. dated April 7, 2010
10.10	(1)*	Non-Plan Stock Option Agreement between Omeros Corporation and Gregory A. Demopoulos, M.D. dated December 11, 2001
10.11	(1)*	Offer Letter between Omeros Corporation and Marcia S. Kelbon, Esq. dated August 16, 2001
10.12	(1)*	Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopoulos, M.D. dated June 16, 1994
10.13	(1)	Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated June 16, 1994
10.14	(1)*	Second Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopoulos, M.D. dated December 11, 2001
10.15	(1)	Second Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated March 22, 2002
10.16	(1)*	Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopoulos, M.D. dated June 16, 1994 (related to tendon splice technology)

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**Exhibit**

<b>Number</b>	<b>Footnote Reference</b>	<b>Description</b>
10.17	(1)	U.S. Bank Centre Office Lease Agreement between Bentall City Centre LLC and Scope International, Inc. dated September 28, 1998
10.18	(1)	Assignment and Amendment of Lease among Omeros Corporation, City Centre Associates and Navigant Consulting, Inc. dated August 1, 2002
10.19	(1)	Second Amendment to Office Lease Agreement between Omeros Corporation and City Centre Associates dated January 4, 2006
10.20	(1)	Lease Agreement between Alexandria Real Estate Equities, Inc. and Primal, Inc. dated April 6, 2000
10.21	(1)	Lease Agreement between Alexandria Real Estate Equities, Inc. and Primal, Inc. dated September 28, 2001
10.22	(1)	Assignment and Assumption and Modification of Lease Documents among Alexandria Real Estate Equities, Inc., Primal, Inc., and nura, inc. dated October 23, 2003
10.23	(1)	Assignment and Assumption and Modification of Lease Documents among Alexandria Real Estate Equities, Inc., nura, inc., and Omeros Corporation dated September 26, 2007
10.24	(4)	Commercial Supply Agreement between Omeros Corporation and Hospira Worldwide, Inc. dated October 9, 2007
10.25	(4)	Exclusive License and Sponsored Research Agreement between Omeros Corporation and the University of Leicester dated June 10, 2004
10.26	(1)	Research and Development Agreement First Amendment between Omeros Corporation and the University of Leicester dated October 1, 2005
10.27	(4)	Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005
10.28	(1)	Amendment dated May 8, 2007 to Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005
10.29	(9)	Funding Agreement between Omeros Corporation and The Stanley Medical Research Institute dated December 18, 2006
10.30	(7)	Landlord Consent to Sublease among Christensen O Connor Johnson Kindness PLLC, City Centre Associates and Omeros Corporation dated January 29, 2008
10.31	(4)	Agreement for Antibody Discovery and Development between Omeros Corporation and Affitech AS dated July 25, 2008
10.32	(9)	Exclusive Technology Option Agreement between Omeros Corporation, Patobios Limited, Susan R. George, M.D., Brian F. O Dowd, Ph.D. and U.S. Bank National Association as escrow agent dated September 4, 2008
10.33	(10)	First Amendment of Exclusive Technology Option Agreement between Omeros Corporation, Patobios Limited, Susan R. George, M.D., Brian F. O Dowd, Ph.D. and U.S. Bank National Association as escrow agent dated November 10, 2009
10.34	(4)	Agreement for Antibody Development between Omeros Corporation and North Coast Biologics LLC dated October 31, 2008
10.35	(4)	Patent Assignment Agreement between Omeros Corporation and Roberto Ciccocioppo, Ph.D. dated February 23, 2009
10.36	(4)*	Omeros Corporation Non-Employee Director Compensation Policy
10.37	(11)	License Agreement between Omeros Corporation and Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.) dated March 3, 2010
10.38	(12)	First Amendment to Agreement for Antibody Discovery and Development between Omeros Corporation and Affitech AS dated March 30, 2010
10.39	(13)	Exclusive License Agreement between Omeros Corporation and Helion Biotech ApS dated April 20, 2010
10.40	(5)	Common Stock Purchase Agreement dated July 28, 2010 between Omeros Corporation and Azimuth Opportunity, Ltd.
10.41	(5)	Engagement Letter dated July 28, 2010 between Omeros Corporation and Reedland Capital Partners

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**Exhibit**

<b>Number</b>	<b>Footnote Reference</b>	<b>Description</b>
10.42	(6)	Loan and Security Agreement between Omeros Corporation and Oxford Finance Corporation dated October 21, 2010
10.43	(6)	Secured Promissory Note issued by Omeros Corporation to Oxford Finance Corporation dated October 21, 2010
10.44		Platform Development Funding Agreement between Omeros Corporation and Vulcan Inc. and its affiliate dated October 21, 2010
10.45		Grant Award Agreement between Omeros Corporation and the Life Sciences Discovery Fund Authority dated October 21, 2010
12.1		Ratio of Earnings to Fixed Charges
21.1	(1)	List of significant subsidiaries of Omeros Corporation
23.1		Consent of Independent Registered Public Accounting Firm
31.1		Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2		Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1		Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2		Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

- (1) Incorporated by reference from the Registration Statement on Form S-1 filed by Omeros Corporation on January 9, 2008 (File No. 333-148572).
- (2) Incorporated by reference from the Annual Report on Form 10-K filed by Omeros Corporation on March 31, 2010 (File No. 001-34475).
- (3) Incorporated by reference from the Registration Statement on Form S-1/A filed by Omeros Corporation on October 2, 2009 (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 July 29, 2010 (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 Registration Statement on Form S-1/A filed by Omeros Corporation on May 15, 2009 (File No. 333-148572).
- (10) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on November 12, 2009 (File No. 001-34475).
- (11) Incorporated by reference from the Quarterly Report on Form 10-Q filed by Omeros Corporation on May 12, 2010 (File No. 001-34475).
- (12) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on March 30, 2010 (File No. 001-34475).
- (13) Incorporated by reference from the Quarterly Report on Form 10-Q filed by Omeros Corporation on August 10, 2010 (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.