

OMEROS CORP  
Form 10-K  
March 31, 2010

**Table of Contents**

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

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2009

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)

**1420 Fifth Avenue, Suite 2600**

**Seattle, Washington**

(Address of principal executive offices)

**98101**

(Zip Code)

**(206) 676-5000**

(Registrant's telephone number, including area code)

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

**Common Stock, \$0.01 par value per share**

(Title of each class)

**The NASDAQ Stock Market LLC**

(Name of each exchange on which registered)

Securities registered pursuant to Section 12(g) of the Act: None

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

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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

Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer

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 registrant's common stock was not publicly traded as of the last business day of the registrant's most recently completed second fiscal quarter. As of March 24, 2010, 21,316,189 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 2010 Annual Meeting of Shareholders to be held May 28, 2010, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2009, are incorporated by reference into Part III of this Form 10-K.

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**OMEROS CORPORATION**  
**ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2009**

**INDEX**

		<u>Page</u>
<b><u>PART I</u></b>		
<u>ITEM 1.</u>	<u>BUSINESS</u>	2
<u>ITEM 1A.</u>	<u>RISK FACTORS</u>	41
<u>ITEM 1B.</u>	<u>UNRESOLVED STAFF COMMENTS</u>	59
<u>ITEM 2.</u>	<u>PROPERTIES</u>	59
<u>ITEM 3.</u>	<u>LEGAL PROCEEDINGS</u>	59
<u>ITEM 4.</u>	<u>RESERVED</u>	60
<b><u>PART II</u></b>		
<u>ITEM 5.</u>	<u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	61
<u>ITEM 6.</u>	<u>SELECTED CONSOLIDATED FINANCIAL DATA</u>	63
<u>ITEM 7.</u>	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	64
<u>ITEM 7A.</u>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	76
<u>ITEM 8.</u>	<u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	76
<u>ITEM 9.</u>	<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	76
<u>ITEM 9A.</u>	<u>CONTROLS AND PROCEDURES</u>	76
<u>ITEM 9B.</u>	<u>OTHER INFORMATION</u>	77
<b><u>PART III</u></b>		
<u>ITEM 10.</u>	<u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	77
<u>ITEM 11.</u>	<u>EXECUTIVE COMPENSATION</u>	77
<u>ITEM 12.</u>	<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS</u>	77
<u>ITEM 13.</u>	<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	78
<u>ITEM 14.</u>	<u>PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	78
<b><u>PART IV</u></b>		
<u>ITEM 15.</u>	<u>EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	79
<u>SIGNATURES</u>		79
<u>EX-3.1</u>		

EX-3.2  
EX-23.1  
EX-31.1  
EX-31.2  
EX-32.1  
EX-32.2

**Table of Contents**

**PART I**

*This Annual Report on Form 10-K contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled Risk Factors and elsewhere in this Annual Report. Please refer to the special note regarding forward-looking statements at the 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 focused on inflammation 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 five ongoing clinical development programs, including four from our PharmacoSurgery platform and one from our Addiction program. Our most advanced clinical development program is in Phase 3 clinical trials. In addition, we have leveraged our expertise in inflammation and the central nervous system to build a deep and diverse pipeline of preclinical programs targeting large markets 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 PharmacoSurgery Platform***

OMS103HP, our lead PharmacoSurgery product candidate, is in two clinical programs. The first is a Phase 3 clinical program, expected to include a total of approximately 1,040 patients, evaluating OMS103HP's safety and ability to improve postoperative joint function and reduce pain following arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery. The second program is evaluating OMS103HP's safety and ability to reduce pain and improve postoperative joint function following arthroscopic meniscectomy surgery. We expect to release the results from our ongoing Phase 3 clinical program for ACL reconstruction surgery during the second half of 2010. 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 recently completed a Phase 1/Phase 2 clinical trial that evaluated the efficacy and safety of OMS302 added to standard irrigation solution and delivered to patients undergoing cataract surgery as well as a Phase 2 concentration-ranging clinical trial of the mydriatic API contained in OMS302 as a mydriasis induction agent. We are finalizing preparations to initiate a second Phase 2 clinical trial for OMS302 to assess the effect of the previously determined concentration of the mydriatic API alone and in combination with varying concentrations of the anti-inflammatory API in a full-factorial design. In addition, we are currently conducting a Phase 1/Phase 2 clinical trial of OMS201 in patients undergoing ureteroscopic removal of ureteral or renal stones.

*Limitations of Current Treatments*

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

## **Table of Contents**

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.

### *Advantages of our PharmacoSurgery Platform*

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) NDA process.

### *Our Addiction Program*

In our Addiction program, we are developing proprietary compositions that include peroxisome proliferator-activated receptor gamma, or PPAR $\gamma$ , agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine, alcohol and amphetamines, as well as other compulsive behaviors. Based on the recently discovered link between PPAR $\gamma$  and addictive disorders together with promising data from European pilot clinical studies and animal models of addiction, we have filed patent applications claiming the use of any PPAR $\gamma$  agonist, alone or in combination with other agents, for the treatment or prevention of addiction and other compulsive behaviors.

In January 2010 we announced that the National Institute on Drug Abuse has agreed to fund substantially all of the costs of a Phase 2 clinical study to evaluate a PPAR $\gamma$  agonist in the treatment of addiction to opioids. This Phase 2 clinical study will be conducted by researchers at the New York State Psychiatric Institute and is expected to begin enrollment in the first half of 2010. We will have the right to reference the data obtained from this study for subsequent submissions to the FDA and will retain all other rights in connection with the Addiction program.

### *Our Preclinical Development Programs*

In addition to our PharmacoSurgery platform and Addiction program, we have a deep and diverse pipeline of preclinical product development programs targeting large market opportunities in inflammation and the CNS.

#### *MASP-2 Program*

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. Our preclinical data suggest that MASP-2 plays a significant role in macular degeneration, ischemia-reperfusion injury associated with myocardial infarction, gastrointestinal ischemia-reperfusion injury, transplant surgery and renal disease, and we have generated several fully human, high-affinity, blocking antibodies to MASP-2.





## **Table of Contents**

### *PDE10 Program*

In our PDE10 program, we are developing proprietary compounds to treat schizophrenia and other psychotic disorders. Results from preclinical animal 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.

### *PDE7 Program*

Our PDE7 program is based on a previously unknown link between PDE7 and any movement disorder, such as Parkinson's disease, or PD, and Restless Legs Syndrome. Based on our promising preclinical animal data in a model of PD showing efficacy of PDE7 inhibitors equivalent to that of levodopa, we are developing proprietary compounds for the treatment of movement disorders. Levodopa has been the standard treatment for PD for nearly 40 years but is associated with severe side effects including dyskinesias, hallucinations, sleep disorders and cognitive impairment, and we believe that our PDE7 inhibitors may avoid one or more of these side effects. We have filed patent applications claiming the use of any PDE7 inhibitor for treating any movement disorder.

### *Our GPCR Program*

We have scientific expertise in the field of G protein-coupled receptors, or GPCRs, and members of our scientific team were the first to identify and characterize all non-sensory GPCRs common to mice and humans. Our work was published in a peer-reviewed article titled "The G protein-coupled receptor repertoires of human and mouse" that appeared in the April 2003 issue of Proceedings of the National Academy of Sciences (Vol. 100, No. 8: pp. 4903-4908). Non-sensory GPCRs are involved in metabolism, behavior, reproduction, development, hormonal homeostasis and regulation of the central nervous system and comprise one of the largest families of proteins in the genomes of multicellular organisms. According to Insight Pharma Reports, 30% to 40% of all drugs sold worldwide target GPCRs. However, based on available data, we believe that there are 363 non-sensory GPCRs of which there are approximately 120 orphans. A non-orphan GPCR is one for which there is a known naturally occurring or synthetic molecule, or ligand, that binds the receptor, while an orphan GPCR has no known ligand. 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.

We hold an exclusive option to acquire all patent and other intellectual property rights to a cellular redistribution assay, or CRA, which we have tested and optimized and that we believe can be used in a high-throughput manner to identify synthetic molecules, including antagonists, agonists and inverse agonists, that bind to 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. Using our expertise and these assets, we believe that we are the first to possess the capability to conduct high-throughput de-orphanization of orphan GPCRs, and that there is no other existing high-throughput technology able to unlock orphan GPCRs. Based on available data, we believe that there may be greater than 65 new druggable targets among the orphan GPCRs. Unlocking these orphan GPCRs could lead to the development of drugs that act at these new targets.

**Table of Contents****Our Product Candidates and Development Programs**

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

<b>Product Candidate/Program</b>	<b>Targeted Procedure/Disease</b>	<b>Development Status</b>	<b>Expected Near-Term Milestone (1)</b>	<b>Worldwide Rights</b>	
<b><i>Clinical Programs</i></b>					
OMS103HP	Arthroscopy	Arthroscopic ACL reconstruction	Phase 3	Complete Phase 3 trials	Omeros
OMS103HP	Arthroscopy	Arthroscopic meniscectomy	Phase 2 completed	Design Phase 3 clinical program	Omeros
OMS302	Ophthalmology	Cataract surgery	Phase 2	Begin enrollment in second Phase 2 trial	Omeros
OMS201	Urology	Ureteroscopy	Phase 1/2	Complete Phase 1/2 trial	Omeros
Addiction		Addiction and other compulsive behaviors	Phase 2	Begin enrollment in Phase 2 trial	Omeros
<b><i>Preclinical Programs</i></b>					
MASP-2		Macular degeneration, ischemia-reperfusion injury, transplant surgery	Preclinical	Select clinical candidate	In-licensed (2)
PDE10		Schizophrenia	Preclinical	Select clinical candidate	Omeros
PDE7		Parkinson's disease, Restless Legs Syndrome	Preclinical	Select clinical candidate	Omeros
<b><i>GPCR Program</i></b>		Multiple disorders	Platform	Surrogate de-orphanization of GPCRs	Omeros

(1) Following selection of a clinical candidate, we must conduct additional studies, including in vivo toxicity studies of the clinical candidate. We must submit the results of these studies, together with manufacturing information and analytical results related to the clinical candidate, to the FDA as part of an IND, which must become effective before we may commence clinical trials. Submission of an IND does not always result in the FDA allowing clinical trials to commence. Depending on the nature of information that we must obtain and include in an IND, it may take from 12 to 24 months from selection of the clinical candidate to IND submission, if it occurs at all. All of these expected near-term milestones are subject to a number of risks, uncertainties and assumptions, including those described in Risk Factors, and may not occur in the timelines set forth above or at all.

(2) 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 and from its collaborator, Medical Research Council at Oxford University.

**Strategy**

Our objective is to become a leading biopharmaceutical company, discovering, developing and successfully commercializing a large portfolio of diverse products. The key elements of our strategy are to:

*Obtain regulatory approval for our late-stage PharmacoSurgery product candidates.*

Each of our PharmacoSurgery product candidates are specifically comprised of APIs contained in generic, FDA-approved drugs with established safety and pharmacological profiles and are delivered to the surgical site in low concentrations with minimal systemic uptake and reduced risk of adverse side effects. All of these product candidates are eligible for submission under the Section 505(b)(2) NDA process.

*Maximize commercial opportunity for our PharmacoSurgery product candidates.*

Our PharmacoSurgery product candidates target large surgical markets with significant unmet medical needs. Because accessing the surgeons who perform the procedures targeted by our

## **Table of Contents**

PharmacoSurgery product candidates may only require a limited, hospital-based marketing and sales force, we believe that we are well positioned to successfully commercialize these product candidates independently or through third-party partnerships.

*Mitigate risk by combining our multiple late-stage PharmacoSurgery product candidates with our deep and diverse pipeline of clinical and preclinical development programs as well as our GPCR program.*

Leveraging our clinical development experience and our expertise in inflammation and the CNS, we have built multiple development programs targeting large markets focused on inflammation and disorders of the CNS as well as the GPCR program focused on unlocking new drug targets. By combining these assets, we believe that our business model mitigates risk by creating multiple opportunities for commercial success.

*Further expand our broad patent portfolio.*

As of March 1, 2010, we owned a total of 21 issued or allowed patents and 31 pending patent applications in the United States, 73 issued or allowed patents and 98 pending patent applications in commercially significant foreign markets, and we also hold worldwide exclusive licenses to two pending United States patent applications, an issued foreign patent and two pending foreign patent applications. We intend to continue to maintain an aggressive intellectual property strategy in the United States and other commercially significant markets.

*Manage our business with continued efficiency and discipline.*

We use rigorous project management techniques to assist us in making disciplined strategic program decisions and to manage the risk profile of our product pipeline. In addition, we plan to continue to seek and access external sources of grant funding to support the development of our pipeline programs and we will consider strategic partnerships to maximize commercial opportunities for our product candidates. We will also continue to evaluate opportunities and, as appropriate, seek to acquire technologies that meet our business objectives.

## **Clinical Programs**

### ***PharmacoSurgery Platform***

#### ***OMS103HP Arthroscopy***

***Background.*** OMS103HP, our lead PharmacoSurgery product candidate, 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. We expect to release the results from this program during the second half of 2010. The second program is evaluating OMS103HP's safety and ability to reduce pain and improve postoperative joint function following arthroscopic meniscectomy surgery. In a recently completed Phase 2 clinical trial in patients undergoing arthroscopic meniscectomy surgery, OMS103HP provided greater efficacy than vehicle as measured by visual analog pain scale (VAS) scores, passive knee flexion and patient reported functional scores (KOOS).

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, swelling, and functional loss. The inflammation associated with arthroscopic surgery, or any other procedure resulting in tissue trauma, is

**Table of Contents**

a complex reaction to tissue injury with multiple pathways, mechanisms and pro-inflammatory mediators, such as PGE<sub>2</sub>, 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 active pharmaceutical ingredients, or APIs, each of which are 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 PGE<sub>2</sub>, 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 PGE<sub>2</sub> 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.

Each of the APIs in OMS103HP 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. Ketoprofen is available as oral OTC and prescription medications, amitriptyline is available as prescription oral and intramuscular medications and oxymetazoline is available as OTC nasal sprays and ophthalmic solutions.

*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 a report that we commissioned from The Reimbursement Group, or TRG, 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.

*Shortcomings of Current Treatments.* There is no drug product currently approved to improve postoperative function following arthroscopic surgery. There are numerous pre- and postoperative approaches



## **Table of Contents**

to reduce postoperative pain and inflammation such as systemically or intra-articularly delivered NSAIDS, opioids, local anesthetics and steroids. Current preoperative treatments are not optimally effective because the administration of standard irrigation solution during the surgical procedure washes out pre-operatively delivered drugs. Intra-articular injections of local anesthetics at the concentrations routinely used, while reducing intra-and immediate postoperative pain, have minimal effect on the local inflammatory cascade. In addition, current postoperative therapies are not optimally effective because the cascade and resultant inflammation, pain, 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 systemically delivered, such as by oral or intravenous administration, to target these problems are frequently associated with adverse side effects. For example, despite the fact that both COX- 1 and COX-2 are drivers of acute inflammation, non-selective COX-1/COX-2 inhibitors are infrequently delivered systemically in the perioperative setting due to risk of increased bleeding associated with COX-1 inhibition.

*Advantages of OMS103HP.* We developed OMS103HP to improve postoperative joint function following arthroscopic surgery by reducing postoperative inflammation and pain. We believe that OMS103HP will provide a number of advantages over current treatments, including:

If approved, OMS103HP will be the first commercially available drug delivered directly to the surgical site to improve function following arthroscopic surgery.

OMS103HP will provide additional postoperative clinical benefits, including improved range of motion, reduced pain and earlier return to work.

OMS103HP selectively targets multiple and discrete pro-inflammatory mediators and pathways within the inflammatory and pain cascade.

By delivering OMS103HP to the joint at the initiation of surgical trauma, the inflammatory and pain cascade will be preemptively inhibited.

Intra-operative delivery to the joint creates a constant concentration of OMS103HP, bathing and replenishing the joint with drug throughout the duration of the surgical procedure.

Because OMS103HP is delivered locally to, and acts directly at, the site of tissue injury, it can be delivered in low concentration, and will not be subject to the substantial interpatient variability in metabolism that is associated with systemic delivery.

By delivering low-concentration OMS103HP locally and only during the arthroscopic procedure, systemic absorption of the APIs will be minimized or avoided, thereby reducing the risk of adverse side effects.

*Development Plan.* We are conducting a Phase 3 clinical program evaluating the efficacy and safety of OMS103HP in patients undergoing arthroscopic ACL reconstruction surgery. The 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). Two trials, each evaluating efficacy and safety of OMS103HP, are being conducted in patients receiving grafts from cadavers or their own tissue, respectively. The safety trial includes 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 our ongoing Phase 3 clinical trials in patients undergoing ACL reconstruction surgery during the second half of 2010.

In our second OMS103HP clinical program, we recently completed a Phase 2 clinical trial evaluating OMS103HP in patients undergoing arthroscopic meniscectomy surgery. We are now preparing to initiate Phase 3 trial design.

*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

**Table of Contents**

OMS103HP and 16 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. Although these positive results are encouraging, there can be no assurance that they will be predictive of the results obtained from later trials.

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 Efficacy ACL Reconstruction.* Key results in the efficacy evaluable population of the Phase 1/Phase 2 clinical trial are as follows:

**Figure 1: OMS103HP-Treated Patients Required Fewer Median Number of Days to Maximum Passive Flexion  $\geq 90^\circ$  without Pain**

\*p = 0.016, log-rank

Figure 1 depicts the median number of days to maximum passive flexion  $\geq 90^\circ$  without pain, which is a knee range of motion test, as measured in the clinic.

**Figure 2: Median Last Day of Continuous Passive Motion Machine Use was Earlier for OMS103HP-Treated Patients**

\*p = 0.007, log rank

Figure 2 depicts the number of days until the continuous passive motion, or CPM, machine was discontinued. CPM machines are often used postoperatively to move the knee through a range of motion. CPM usage, recorded in the patient diary, was discontinued at the direction of either the surgeon or rehabilitation therapist based on the patient's progress, usually at the time the patient reproducibly attained at least  $90^\circ$  of flexion of the operated knee. CPM machine usage was significantly less for OMS103HP.

**Table of Contents****Figure 3: OMS103HP-Treated Patients Demonstrated Better Quadriceps Strength Testing at Day 30**

\*p = 0.040, FET

Figures 3 and 4 depict the strength of the quadriceps and hamstring muscle groups of the operated leg as evaluated by the surgeon at the end of the 30-day evaluation period. Quadricep and hamstring strength testing was evaluated on a scale of 0/5 (no contraction) to 5/5 (normal strength). This was a qualitative clinical evaluation of muscle function and strength. Pre-operative quadriceps and hamstring muscle strength ratings were similar for both patient groups.

**Figure 5: A Greater Percentage of OMS103HP-Treated Patients Demonstrated Successful Recovery of Knee Function as Defined by Knee Function Composite**

\*p = 0.026, FET

Figure 5 depicts the study's primary endpoint, the Knee Function Composite, or KFC. The KFC is composed of the straight-leg raise, one-leg stance, shuttle press, and two-leg squat. Each test is a direct measure of knee function, and all four are routinely used by orthopedic surgeons and rehabilitation therapists to measure improvement in knee function during the early postoperative period following ACL reconstruction surgery. Success on the KFC requires success on all four of the component tests by the end of the 30-day evaluation period.

**Figure 4: OMS103HP-Treated Patients Demonstrated Better Hamstring Strength Testing at Day 30**

\*p = 0.026, FET

**Figure 6: A Greater Percentage of OMS103HP-Treated Patients Demonstrated Very Good and Good Ratings on the Knee Function Composite Straight-Leg Raise**

\*p = 0.009, Wilcoxon rank sum test

*Very Good:* Achievement of the KFC by the end of the 30-day evaluation period and achievement of the highest level of straight-leg raise, or SLR, by the 13th day after surgery  
*Good:* Achievement of the KFC by the end of the 30-day evaluation period without achievement of the highest level of SLR by the 13th day after surgery  
*Poor:* Failure to achieve the KFC by the end of the 30-day evaluation period

Figure 6 depicts the Knee Function Composite Straight-Leg Raise, or KFC-SLR, which combines the successful achievement of the KFC with a second key rehabilitation milestone, the ability to perform the highest level of the straight-leg raise by the 13th day after surgery following ACL reconstruction surgery. While the KFC accurately assesses knee function throughout the first 30-day period of postoperative rehabilitation therapy, an evaluation of postoperative function within the first two weeks also is important because early functional return is considered a key driver in successful post-arthroscopy outcomes. Of the four tests comprising the KFC, the straight-leg raise is the most important in the first two weeks following ACL reconstruction because it is used to determine the pace to progress exercises. (

( As published in *Arthroscopy: The Journal of Arthroscopic and Related Surgery*, Vol. 24, No. 6 (June), 2008: pp. 625-636.

**Table of Contents**

**Figure 7: A Greater Percentage of OMS103HP-Treated Patients Achieved Successful Pain Management at Postoperative Week 1**

\*p = 0.031, FET

Figure 7 depicts the percentage of patients achieving Successful Pain Management, or SPM, which is a composite of pain assessment and narcotic usage based on data from clinic visits and the patient diary. The SPM composite sets two criteria that the patient must meet in order to be considered a responder. During the first postoperative week, at all clinic visits, the VAS pain score must be not greater than 20 mm with the operated knee at rest. A maximum of two narcotic tablets could be self-administered on each day during the first postoperative week. VAS pain scores of 20 mm or less are considered to be indicative of good to excellent pain control not requiring analgesic medication. The SPM allows pain assessments and narcotic use to be evaluated together, and provides a more complete evaluation of pain management than either VAS pain scores or narcotic usage considered individually because a low VAS pain score recorded by a patient taking high doses of opioid pain medications does not reflect the same level of pain management as that same low VAS pain score recorded in the absence of narcotic pain medications.

**Figure 8: OMS103HP-Treated Patients Demonstrated a Lower Median Number of Days to Return to Work**

\*p = 0.048; log-rank test

Figure 8 depicts results related to patients' ability to return to work following ACL reconstruction surgery. Patients were considered to have returned to work if they reported in the patient diary that they had gone to work outside of the home on two consecutive work days excluding weekends and holidays. Return to work was considered to have begun on the first of the two consecutive days. Patients who were unemployed or not working for pay were excluded from the analysis.

As published in *Arthroscopy: The Journal of Arthroscopic and Related Surgery*, Vol. 24, No. 6 (June), 2008: pp. 625-636.

*Clinical Trial Results Safety ACL Reconstruction.* 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.

*Clinical Trial Results Meniscectomy.* We conducted a multicenter, randomized, double-blind, vehicle-controlled Phase 2 clinical trial of OMS103HP in patients undergoing arthroscopic 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.

This study has shown that OMS103HP provides greater efficacy than vehicle as measured by visual analog scale, or VAS, pain scores, passive knee flexion and patient reported functional scores using the Knee Injury and Osteoarthritis Outcome Score, or KOOS. 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.

Pain scores in the immediate 24-hour period and up to seven days postoperatively were measured using a validated, 100-point, VAS. Range of motion assessments were made at baseline and day seven postoperatively. The protocol

was amended to collect patient self reports using the 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).

*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 active pharmaceutical ingredient, or API, and an API that causes pupil

**Table of Contents**

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.

During lens replacement surgery, a small ultrasonic probe, or a phacoemulsifier, is typically used to help remove the lens. In these procedures, the surgeon first places a small incision at the edge of the cornea and then creates an opening in the membrane, or capsule, surrounding the damaged lens. Through the small corneal incision, the surgeon inserts the phacoemulsifier, breaking the lens into tiny fragments that are suctioned out of the capsule by the phacoemulsifier. After the lens fragments are removed, an artificial intraocular lens is implanted with a small injector that is inserted through the same corneal incision.

*Market Opportunity.* According to Thomson Healthcare, approximately a total of 2.9 million cataract operations were performed in the United States in 2006. Based on a report that we commissioned from TRG, we believe that OMS302 will be favorably reimbursed both to the surgical facility for its utilization and to the surgeon for its administration and delivery. Also, use of OMS302 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 OMS302 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. We also believe that use of OMS302 will increase the ease of the surgical procedure, thereby increasing patient throughput for both the surgeon and the surgical facility.

*Shortcomings of Current Treatments.* Anti-inflammatory topical drops containing NSAIDs, such as Acular-LS<sup>®</sup>, Acular<sup>®</sup>, Voltaren<sup>®</sup> and Xibrom<sup>®</sup>, or steroids are routinely used postoperatively, and less frequently pre-operatively, to prevent or manage the intra- and postoperative pain and inflammation associated with lens replacement surgery. Pre-operatively, these topical drops are not optimally effective because the continuous administration of standard surgical irrigation solution washes out pre-operatively delivered drugs. Postoperatively, these anti-inflammatory topical drops typically cannot be delivered until at least 24 hours following surgery due to practical constraints and safety concerns. Further, surgical trauma results in the generation of prostaglandins, which cause miosis during lens replacement surgery. NSAIDs have an inhibitory effect on prostaglandin synthesis and, if this inhibitory effect is not present during the trauma of lens replacement surgery, the risk of miosis increases.

Cataract and other lens replacement surgery requires that the pupil be dilated for the surgeon to perform the procedure efficiently and safely. Topical mydriatic drops are usually delivered by surgical staff to the patient in a pre-operative holding area. If mydriasis is 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. Further, many patients who undergo cataract surgery also take alpha adrenergic antagonists, such as FLOMAX<sup>®</sup>, to reduce urinary frequency and other signs and symptoms associated with prostate enlargement. These patients often demonstrate a reduced response to topically applied mydriatic drops, causing the pupil to not fully dilate and leaving the iris, or the pigmented ring in the eye that surrounds the pupil, flaccid. Referred to as intra-operative floppy iris syndrome, this complicates and decreases the safety of cataract surgery, and puts the iris at risk of surgical tear and other damage.





**Table of Contents**

*Advantages of OMS302.* We developed OMS302 for use during cataract and other lens replacement surgery to maintain mydriasis, to prevent surgical miosis and to reduce postoperative pain and irritation. We believe that OMS302 will provide a number of advantages over current treatments, including:

The anti-inflammatory API in OMS302 inhibits miosis by blocking the synthesis of prostaglandins caused by surgical trauma.

By delivering OMS302 intra-operatively, inflammation and discomfort will be reduced during the first 24 hours following surgery, the time during which anti-inflammatory topical drops are not commonly administered, as well as after this initial postoperative period.

Intra-operative delivery of the mydriatic API in OMS302 will maintain pupil dilation throughout the surgical procedure, decreasing the risk of surgical damage to structures within the eye.

Because the mydriatic API in OMS302 maintains pupil dilation, OMS302 will increase the ease of the surgical procedure, thereby increasing patient throughput for both the surgeon and the surgical facility.

The mydriatic API in OMS302 prevents intra-operative floppy iris syndrome in many patients taking alpha adrenergic antagonists, such as FLOMAX®.

Because OMS302 is delivered intracamerally in standard irrigation solution at a constant, defined concentration, maintaining a more consistent local tissue exposure during the surgical procedure, it will provide superior efficacy relative to topical drug products containing either API.

OMS302 is delivered locally to, and acts directly at, the site of tissue injury and, therefore, can be delivered in low concentrations, and will not be subject to the substantial interpatient variability in pharmacokinetics that is associated with systemic delivery.

*Development Plan.* We recently completed a Phase 1/Phase 2 clinical trial that evaluated the efficacy and safety of OMS302 added to standard irrigation solution and delivered to patients undergoing cataract surgery as well as a Phase 2 concentration-ranging clinical trial of the mydriatic API contained in OMS302 as a mydriasis induction agent. We are finalizing preparations to initiate a second Phase 2 clinical trial for OMS302 to assess the effect of the previously determined concentration of the mydriatic API alone and in combination with varying concentrations of the anti-inflammatory API in a full-factorial design. These trials will serve as the basis for additional trials intended to establish OMS302 as an effective and safe replacement for currently used ophthalmologic drugs.

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

following surgery. The effects of OMS302 on direct measures of inflammation will be evaluated in additional planned studies.

**Table of Contents**

*Clinical Trial Results Efficacy.* Key results from the Phase 1/Phase 2 clinical trial are as follows:

**Figure 1: Pupil Size Relative to Start Time of Irrigation**

Figure 1 depicts that OMS302 and OMS302-mydriatic were both better than vehicle control in measures of mydriasis during the surgery, evident after 10 minutes, following the start of irrigation.

**Table of Contents**

**Figure 2: Proportion of Patients with No Ocular Pain Reported**

Figure 2 depicts patient-reported measures of pain following cataract surgery. Patients treated with OMS302 reported less pain than patients treated with either OMS302-mydratic or vehicle control over the first 16 hours immediately following surgery.

*Clinical Trial Results Safety.* 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-mydratic group) reported mild to moderate eye pain judged by the investigator to be either possibly or probably treatment-related.

*OMS201 Urology*

*Background.* OMS201 is our PharmacoSurgery product candidate being developed for use during urological surgery, including uroendoscopic procedures. OMS201 is a proprietary combination of an anti-inflammatory active pharmaceutical ingredient, or 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 with well-known profiles of safety and pharmacologic activities, and each has been individually prescribed to manage the symptoms of ureteral and renal stones. Each of the APIs in OMS201 is contained in drugs that have been marketed in the United States for more than 15 years.

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. 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

**Table of Contents**

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.

Ureteroscopy, or uroendoscopy of the ureter, is performed for a variety of indications including localizing the source of positive urine culture or cytology results, treating upper urinary tract tumors and obstructions, and removing ureteral and renal stones, particularly in those patients for whom non-surgical procedures are insufficient or unsuitable. Irrigation fluid is used continuously during the procedure. Because ureteroscopic trauma and inflammation can result in constrictive scar tissue, or stricture, and pain and occlusion due to smooth muscle spasm and swelling within the lumen of the ureter, most surgeons routinely place ureteral stents in patients following ureteroscopy to prevent ureteral strictures and occlusion. In addition, during ureteroscopy, many surgeons commonly place a ureteral access sheath, or UAS, which helps to protect the lining of the urethra and ureter while facilitating the passage of surgical instruments.

*Market Opportunity.* According to Thomson Healthcare, approximately a total of 4.3 million uroendoscopic operations were performed in the United States in 2006. Based on a report that we commissioned from TRG, we believe that OMS201 will be favorably reimbursed both to the surgical facility for its utilization and to the surgeon for its administration and delivery. Also, use of OMS201 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 OMS201 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.

*Shortcomings of Current Treatments.* Standard irrigation solutions currently delivered during uroendoscopic procedures do not address problems resulting from surgically induced inflammation, pain and smooth muscle spasm, or excess contractility. In addition, routine use of stents following ureteroscopy to prevent ureteral strictures and occlusion adds to procedural costs, and is itself traumatic, increasing postoperative inflammation and ureteral spasm. Further, patients with stents resident within the ureter experience significantly more flank and bladder pain, increased lower urinary tract symptoms and increased narcotic usage.

In addition, during ureteroscopy, the selection of UAS size is based on the diameter and muscle tone of a patient's ureter. The benefits of UAS usage are in large part a direct function of increased UAS diameter; however, there are no routinely used intra-operative treatments to increase ureteral diameter or decrease ureteral muscle tone. Many patients are unable to accommodate a larger-sized UAS, requiring that the surgeon use a smaller-sized UAS or none at all, putting those patients at increased risk for intra- and postoperative problems.

*Advantages of OMS201.* We developed OMS201 for use during uroendoscopic procedures such as cystoscopy, minimally invasive prostate surgery and ureteroscopy, to inhibit surgically induced inflammation, pain and smooth muscle spasm. We believe that OMS201 will provide a number of advantages over current treatments, including:

By delivering OMS201 intra-operatively, it will reduce inflammation, pain, smooth muscle spasm and lower urinary tract symptoms including frequency, urgency and painful urination, and improve patient outcomes.

OMS201 will save health care costs and increase patient comfort by reducing the incidence of ureteral occlusion and the routine need for ureteral stents.

By targeting inflammation and smooth muscle spasm, OMS201 will permit surgeons to more frequently place a standard larger-sized UAS, decreasing intra-operative trauma and shortening operative time, thereby saving costs.

OMS201 is delivered locally to, and acts directly at, the site of tissue injury and, therefore, can be delivered in low concentrations, and will not be subject to the substantial interpatient variability in pharmacokinetics that is associated with systemic delivery.

By delivering OMS201 locally and only during the uroendoscopic procedure, systemic absorption of the APIs will be minimized or avoided, thereby reducing the risk of adverse side effects.

**Table of Contents**

*Development Plan.* Based on our successfully completed Phase 1 clinical trial, we are now conducting a Phase 1/Phase 2 clinical trial evaluating the efficacy, safety and systemic absorption of potentially two sequentially higher concentrations of OMS201 added to standard irrigation solution and delivered to patients undergoing UAS-assisted ureteroscopy for removal of ureteral or renal stones.

The primary objective of this clinical trial is to assess the pharmacokinetics and safety of higher concentrations of OMS201 than those evaluated in the Phase 1 trial. In addition, to assist in designing the Phase 2 clinical protocol, we are evaluating efficacy endpoints directed to ease of surgery, including the size of the UAS that can be used during the procedure, the time it takes to complete the procedure and the overall surgical outcome during the first postoperative week, as well as monitoring postoperative pain, pain medication usage and lower urinary tract symptoms. We expect to complete the Phase 1/Phase 2 clinical trial of OMS201 in mid-2010.

*Clinical Trial Results.* We conducted a randomized, double-blind, vehicle controlled and parallel-assigned Phase 1 clinical trial to evaluate the systemic absorption and safety of OMS201 in patients receiving primary treatment by endoscopic removal of urinary stones. The pharmacokinetic data from this study show that systemic plasma levels of the active agents of OMS201 in patients were minimal or below the level of quantification. There were no serious adverse events.

***Addiction Program***

In our Addiction program, we are developing proprietary compositions that include peroxisome proliferator-activated receptor gamma, or PPAR  $\gamma$ , agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine, alcohol and amphetamines, as well as other compulsive behaviors. Based on the recently discovered link between PPAR  $\gamma$  and addictive disorders together with promising data from European pilot clinical studies and animal models of addiction, we have filed patent applications claiming the use of any PPAR  $\gamma$  agonist, alone or in combination with other agents, for the treatment or prevention of addiction and other compulsive behaviors.

In January 2010 we announced that the National Institute on Drug Abuse has agreed to fund substantially all of the costs of a Phase 2 clinical study to evaluate a PPAR  $\gamma$  agonist in the treatment of addiction to opioids. This Phase 2 clinical study will be conducted by researchers at the New York State Psychiatric Institute and is expected to begin enrollment in the first half of 2010. We will have the right to reference the data obtained from this study for subsequent submissions to the FDA and will retain all other rights in connection with the Addiction program.

*Alcohol and Nicotine Addiction.* Our preclinical data from rat models of alcohol and nicotine addiction demonstrated that administration of a PPAR  $\gamma$  agonist significantly reduced (1) the voluntary intake or administration of both alcohol and nicotine in the respective substance-conditioned animals, (2) stress-induced relapse to alcohol- and nicotine-seeking behavior and (3) alcohol and nicotine withdrawal symptoms.



**Table of Contents**

**Figure 1: PPAR Agonist in Animal Model of Alcohol Addiction**

Figure 1 illustrates the effect of treatment with a PPAR agonist in a rat model of alcohol addiction. As compared to vehicle control, the administration of a PPAR agonist significantly reduced the voluntary intake of alcohol in alcohol conditioned animals. It also significantly reduced stress-induced relapse to alcohol-seeking behavior and alcohol withdrawal symptoms (data not shown).

**Figure 2: PPAR Agonist in Animal Model of Nicotine Addiction**

Figure 2 illustrates the effect of treatment with a PPAR agonist in a rat model of nicotine addiction. As compared to vehicle control, the administration of a PPAR agonist significantly reduced the voluntary administration of nicotine in nicotine-conditioned animals. It also significantly reduced stress-induced relapse to nicotine-seeking behavior and nicotine withdrawal symptoms (data not shown).

On the basis of these studies, small pilot clinical studies were performed in Europe to evaluate the effect of a PPAR agonist on both alcohol and nicotine addiction. A small open label study compared the effects on alcohol consumption across three four-patient groups: (1) treatment with a PPAR agonist together with

**Table of Contents**

counseling, (2) an approved drug for the treatment of alcohol addiction plus counseling and (3) counseling alone. Daily drink reduction over a two-month period was significantly better for patients in the two groups receiving pharmacologic treatment than for patients receiving counseling alone. All patients in the group treated with the PPAR agonist became alcohol abstinent within three months of treatment initiation, continued abstinence for the duration of the 11-month drug treatment and have remained abstinent with only counseling at five months following completion of drug treatment. In contrast, patients receiving the approved anti-addiction drug either failed to reach abstinence or dropped out of the study by 26 weeks, and the patients receiving counseling alone did not substantively reduce their alcohol intake and dropped out of the study after the initial two-month period.

Another of our pilot clinical studies evaluated the effect of a PPAR agonist on nicotine addiction. This small open label study compared the effect on tobacco use among three groups consisting of three to four patients each. The first group received a PPAR agonist, the second group was treated with an approved smoking-cessation drug with known CNS side effects (e.g., depression, agitation, suicidal ideation) and the third group was given an antidepressant drug approved for smoking cessation. Patients receiving either the PPAR agonist or the conventional anti-smoking drug exhibited a similar substantial reduction in smoking following two months of treatment. Although small in sample size, none of the patients treated with the PPAR agonist demonstrated the side effects known to be associated with the conventional anti-smoking drug. Smoking reduction for each of these two groups was substantially higher than for patients receiving the antidepressant drug approved for smoking cessation.

*Opioid Addiction.* In addition to potentially treating existing addictive behaviors, PPAR agonists may prevent addiction. Another of our preclinical studies evaluated the effects of daily treatment with a representative PPAR agonist compared to a vehicle control on acquisition of addiction to heroin in an animal model of heroin self-administration. While the desire for and resulting self-administration of heroin by animals treated with the control progressively increased during the eight-day study, animals treated daily with the PPAR agonist demonstrated complete ablation of heroin acquisition. The same animals tested in the heroin self-administration model were also tested in a food self-administration model, providing a positive control to evaluate whether the PPAR agonist affected the animals' ability to perform the self-administration. The representative PPAR agonist did not affect the animals' food acquisition, indicating that the PPAR agonist's effects in this study using the heroin self-administration model were not due to any cognitive, memory or functional impairment.

To further evaluate the potential for PPAR agonists to be administered in combination with opioids to prevent addiction to the opioids, an additional preclinical study in animals evaluated the analgesic effects of a combination of a PPAR agonist with morphine, an opioid routinely used for pain management. A limitation of morphine when used to treat chronic pain is the development of tolerance, resulting in the need for increasing dosages to achieve pain relief. Eventually, the dosage cannot safely be increased any further and morphine does not provide adequate pain relief to the patient. In two different rat models of pain and analgesia, the combination of morphine and a PPAR agonist administered over a nine-day test period did not alter the analgesic effect of morphine and the combination improved the analgesic effect as compared to morphine alone, suggesting that the PPAR agonist delayed the development of tolerance to morphine.

**Table of Contents**

**Figure 3: PPAR Agonist in Animal Model of Heroin Self-Administration**

Figure 3 illustrates the effects of daily treatment with a representative PPAR agonist compared to a vehicle control on acquisition of addiction to the opioid agent, heroin, in an animal model of heroin self-administration. While the desire for and resulting self-administration of heroin by animals treated with the control progressively increased during the eight-day study, animals treated daily with the PPAR agonist demonstrated complete ablation of heroin acquisition.

**Figure 4: PPAR Agonist in Animal Model of Food Self-Administration**

The same animals tested in the heroin self-administration model were tested in a food self-administration model, providing a positive control. Figure 4 demonstrates that the representative PPAR agonist administered in both models did not affect the animals' food acquisition and that, therefore, the PPAR agonist effects in the heroin self-administration model were not due to cognitive, memory or functional impairment.

Anecdotal clinical case reports also suggest that PPAR agonists may be useful in the treatment of opioid addiction. While these case reports and the other open-label pilot studies evaluating alcohol and nicotine addiction discussed above are not as predictive as blinded studies, they suggest PPAR agonists may be useful for the treatment of addictive disorders.

There are currently no medications to prevent addiction, and many widely prescribed drugs, including opioids, anxiolytics, sleep-inducing agents and stimulants, are highly addictive. Our findings suggest that the combination of a PPAR agonist with a prescription medication may result in a reduced potential for abuse of the prescription medication. In addition, a single formulation combining a PPAR agonist with any drug of abuse may result in significantly greater patient compliance than co-administration of the two agents

## **Table of Contents**

individually. Our data also suggest the possibility that combinations of a PPAR agonist with other conventional drugs used to treat addiction may be more effective than either agent alone.

Although these positive results from our animal studies, pilot clinical studies and anecdotal case reports are encouraging, there can be no assurance that they will be predictive of the results obtained from later studies or trials.

We acquired the patent applications and related intellectual property rights for our Addiction program in February 2009 from Roberto Ciccocioppo, Ph.D. of the Università di Camerino, Italy, pursuant to a Patent Assignment Agreement. Under this agreement, we have agreed to pay Dr. Ciccocioppo a low-single digit percentage royalty on net sales of any products that are covered by any patents that issue from the patent applications that we acquired from him. In addition, if we grant any third parties rights to manufacture, sell or distribute any such products, we must pay to Dr. Ciccocioppo a percentage of any associated fees we receive from such third parties in the range of low single-digits to low double-digits depending on stage of development at which such rights are granted. We have also agreed to make milestone payments of up to \$2.3 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.

## **Preclinical Programs**

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

A discovery by researchers at the University of Leicester led to the identification of mannan-binding lectin-associated serine protease-2, or MASP-2, a novel pro-inflammatory protein target in the complement system. 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 and from its collaborator, Medical Research Council at Oxford University. MASP-2 is a key protein involved in activation of the complement system, which is an important component of the immune system. The complement system plays a role in the inflammatory response and becomes activated as a result of tissue damage or trauma or microbial pathogen invasion. MASP-2 appears to be unique to, and required for the function of, one of the principal complement activation pathways, known as the lectin pathway. Importantly, inhibition of MASP-2 does not appear to interfere with the antibody-dependent classical complement activation pathway, which is a critical component of the acquired immune response to infection, and its abnormal function is associated with a wide range of autoimmune disorders.

In our MASP-2 program, we are developing MASP-2 antibody therapies to treat disorders caused by complement-activated inflammation. 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. We evaluated the role of MASP-2 in wet age-related macular degeneration, or wet AMD, using a mouse model of laser-induced choroidal neovascularization, or CNV. CNV refers to the growth of blood vessels into the light-sensing cell layers of the eye and is a pathologic event underlying the severe vision loss associated with wet AMD. In comparison to isotype control antibodies, systemic administration of MASP-2 antibodies to mice produced a

dose-dependent reduction with a maximal effect of approximately 50% inhibition in CNV. Our findings suggest that antibody-blockade of MASP-2 may have a preventive or therapeutic effect in the treatment of wet AMD.

Another set of studies evaluated the role of MASP-2 in ischemia-reperfusion injury. Ischemia is the interruption of blood flow to tissue, and reperfusion of the ischemic tissue results in inflammation and oxidative

**Table of Contents**

stress leading to tissue damage. Ischemia-reperfusion injury occurs, for example, following myocardial infarction, coronary artery bypass grafting, aortic aneurysm repair, stroke, organ transplantation or gastrointestinal vascular injury. In a mouse model of gastrointestinal ischemia-reperfusion injury, the loss of intestinal barrier function was assessed by surgical clamping of the artery that supplies the large intestine followed by reperfusion after removal of the clamp. While animals treated only with saline or an isotype control antibody exhibited a substantial loss of intestinal barrier function as compared to animals in which a sham procedure that did not include arterial clamping was performed, treatment of animals with MASP-2 antibodies prior to ischemia-reperfusion resulted in statistically significant preservation of intestinal barrier function. In another study using a mouse model of myocardial ischemia-reperfusion injury, we compared the outcomes of coronary artery occlusion followed by reperfusion in both MASP-2 knock-out mice and wild-type mice. The MASP-2 knock-out mice displayed a statistically significant reduction in myocardial tissue injury versus the wild-type mice, indicating a protective effect from myocardial ischemia reperfusion damage in the MASP-2 knock-out mice in this model. An additional study in a model of renal ischemia-reperfusion injury also demonstrated a protective effect in MASP-2 knock-out mice. We are continuing to evaluate the role of MASP-2 in stroke, sepsis and other complement-mediated 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 undertaken the development of MASP-2 antibodies with two independent antibody developers, Affitech AS and North Coast Biologics. Working with an external antibody development company under license for research use, we have generated several fully human MASP-2 antibody fragments, or Fab2s, that show high affinity for MASP-2. We demonstrated functional blockade of the lectin complement activation pathway in normal human serum by several of these human Fab2s with picomolar potency.

**Figure 1: Effect of a Single Dose of Systemically Delivered MASP-2 Antibody on CNV in Mouse Model**

Figure 1 depicts that systemic administration of MASP-2 antibody produced an approximately 50% inhibition in the area of CNV, a significant pathological component of wet AMD, compared to isotype control antibody-treated mice seven days following laser-induced damage. The statistically significant reduction in CNV with the MASP-2 antibody compared to isotype control antibody suggests that blockade of MASP-2 may have a preventive or therapeutic effect in the treatment of macular degeneration.

**Table of Contents**

**Figure 2: Effect of MASP-2 Antibody on Organ Damage in Mouse Model of Gastrointestinal Ischemia-Reperfusion Injury**

Figure 2 illustrates that a MASP-2 antibody protects mice from loss of intestinal barrier function following ischemia-reperfusion injury. The artery that supplies the large intestine was clamped for 20 minutes, followed by three hours of reperfusion after removal of the clamp. Three groups of animals were treated with a saline control, a MASP-2 antibody or an isotype control antibody prior to ischemia-reperfusion, while a fourth group had only a sham procedure that did not involve clamping. Saline-treated control and isotype control treated animals showed a substantial loss of intestinal barrier function as compared to sham animals, while MASP-2 antibody-treated animals exhibited a significant preservation of function.

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. Each license agreement can also be terminated by us if the University of Leicester or MRC, as applicable, is unable to establish title to joint ownership rights to patents and patent applications obtained or filed by researchers at Aarhus Universitet related to MASP- 2 that are based in part on the results of research conducted by the University of Leicester, MRC and these researchers.

**Table of Contents**

***PDE10 Program***

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 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.

We obtained the PDE10 program as part of our nura acquisition in 2006, and we have synthesized a series of chemical classes yielding multiple proprietary compounds that demonstrate promising preclinical results in pharmacokinetic, pharmacodynamic and behavioral studies. 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. As of December 31, 2009, we have received \$5.7 million from SMRI, \$1.8 million of which was recorded as revenue, \$3.2 was recorded as equity funding and \$702,000 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, 2009, 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.

**Figure 1: Preclinical Efficacy Studies of one of our PDE10 Compounds in Mice**

Figure 1 demonstrates that oral administration of one of our PDE10 inhibitors, OMS182410, in mice, improved the response in the conditioned avoidance response test, a commonly used assay that measures the avoidance response of a conditioned animal that has been trained to associate a visual cue (e.g., light) with an unpleasant experience (e.g., electric shock). Antipsychotics are known to reduce avoidance.



**Table of Contents**

***PDE7 Program***

Our Phosphodiesterase 7, or PDE7, program is based on our demonstration of a previously unknown link between PDE7 and any movement disorder, such as Parkinson's disease, or PD, and Restless Legs Syndrome, or RLS. PDE7 is highly expressed in those regions of the brain associated with movement disorders. We believe that the mechanism of action for PDE7 inhibitors is different from that of all currently available drugs for PD and RLS, such as levodopa, or L-DOPA, and related dopamine agonists, and therefore PDE7 inhibitors may avoid one or more of the debilitating side effects associated with these agents. We have filed patent applications claiming the use of any PDE7 inhibitor for treating any movement disorder.

Using an established model of PD, we investigated the effects of multiple PDE7 inhibitors in mice lesioned with the chemical MPTP. MPTP destroys dopaminergic neurons in specific regions of the brain, pathologically mimicking PD and resulting in reduced stride length, a common finding in PD patients. Administration of PDE7 inhibitors to MPTP-treated mice restored stride length to pre-lesioned levels within 30 minutes, and did so at doses 50- to 100- fold lower than that of equally effective doses of L-DOPA. Our data also shows that PDE7 inhibitors potentiate the activity of L-DOPA.

**Figure 1: Efficacy in Animal Model of Parkinson's Disease of a PDE7 Inhibitor**

Figure 1 depicts that, in a mouse MPTP-stride length model of PD, a representative PDE7 inhibitor is equally effective to and greater than 50-fold more potent than L-DOPA. Subtherapeutic doses of both the PDE7 inhibitor and L-DOPA, in combination, resulted in efficacy greater than the expected sum of the effects of the individual agents, demonstrating the potentiation of L-DOPA's effect.

Based on our existing data, we believe that PDE7 inhibitors may provide an alternative to treatment with L-DOPA or related PD drugs, or could be used in conjunction with these agents at lower doses than they are currently used, potentially reducing side effects including hallucinations, somnolence, cognitive impairment and involuntary movements, or dyskinesias. Further, because L-DOPA and other related PD drugs are agonists, they are associated with the development of tolerance, which is not a problem commonly associated with inhibitors. We currently are conducting additional studies evaluating the effects of potential clinical candidates in models of Parkinson's disease and other CNS disorders.

The Michael J. Fox Foundation, or MJFF, provided grant funding for some of our preclinical studies to cover our actual costs incurred, up to a total of \$464,000. In consideration of MJFF's grant funding, we have

## **Table of Contents**

agreed to provide MJFF limited rights to access the data from these studies. We are not obligated to pay MJFF any royalties or other consideration as a result of the grant funding.

On March 3, 2010, we entered into a license agreement with Asubio Pharma Co., Ltd., or Asubio, pursuant to which we received an exclusive license to PDE7 inhibitors claimed in certain patents and pending patent applications owned by Asubio for use in the treatment of movement disorders and other specified indications. Under the agreement, we agreed to make milestone payments to Asubio 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, Asubio 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 Asubio 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 Asubio 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. Asubio 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 Asubio's patents will revert to Asubio.

## **GPCR Program**

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.

It is estimated that worldwide annual drug sales exceed \$700 billion, and 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. Based on available data, we believe that there may be greater than 65 new druggable targets among the 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, there has previously been no commercially viable technology to de-orphanize 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, we hold an exclusive option from Patobios Limited to acquire all of its

**Table of Contents**

patent and other intellectual property rights to a cellular redistribution assay, or CRA, which we have tested and optimized and that we believe can be used in a high-throughput manner to identify molecules, including antagonists, agonists and inverse agonists, that bind to orphan GPCRs, or surrogate de-orphanization of orphan GPCRs. Surrogate de-orphanization is the identification of synthetic molecules, as opposed to endogenous or naturally occurring ligands, that bind to orphan GPCRs. We also have developed a proprietary rapid mouse gene knock-out platform technology, which is described in a peer-reviewed article titled "Large-scale, saturating insertional mutagenesis of the mouse genome" that appeared in the September 2007 issue of Proceedings of the National Academy of Sciences (Vol. 104, No. 36: pp. 14406-14411). We have used this platform to create 61 different GPCR-specific strains of knock-out mice, and we have established a battery of behavioral tests that allows us to characterize these knock-out mice and identify candidate drug targets. The genes disrupted in these strains of knock-out mice include those linked to orphan GPCRs. In addition, we have developed a platform technology to efficiently produce reversible and inducible mouse gene knockout and rescue, which allows the mouse to fully develop before knocking out the gene rather than creating the knockout in the mouse embryo. As a result, we can evaluate the function of a gene even when its mutation would cause compensation by other genes or death during embryonic or neonatal development. This platform technology is described in a peer-reviewed article titled "An Inducible and Reversible Mouse Genetic Rescue System" that appeared in the May 2008 issue of PLoS Genetics (Vol. 4, Issue. 5).

Using our expertise and these assets, we believe that we are the first to possess the capability to conduct high-throughput surrogate de-orphanization of orphan GPCRs, and that there is no other existing high-throughput technology able to "unlock" orphan GPCRs. Based on our ability to de-orphanize orphan GPCRs through the identification of multiple binding molecules, identify their respective signaling pathways and generate and characterize the associated knock-out mice, we intend to seek strong and exclusive intellectual property positions around these de-orphanized GPCRs.

In addition to their importance in humans, GPCRs are also present in other multicellular organisms, including other animals, plants and disease pathogens. Many of these GPCRs are orphans and are amenable to our de-orphanization capabilities. We believe that our GPCR platform technology can allow the development of a new generation of safer and more effective insecticides and drugs selectively targeting the offending organisms' GPCRs for the prevention and treatment of tropical infections and diseases, including parasitic infections such as those caused by flatworms and vector-borne diseases such as malaria and Dengue fever, as well as pesticides for agricultural use and therapeutics for animal husbandry.

In addition to our plans to conduct surrogate de-orphanization, we have identified what we believe to be previously unknown links between specific GPCR targets in the brain and a series of CNS disorders, and plan to discover additional links between these and other GPCRs and a wide range of disorders, including behavioral, cardiac, endocrine, gastrointestinal, immunologic, metabolic, musculoskeletal, oncologic, renal and respiratory. We have filed, and plan to file, corresponding patent applications related to these previously unknown links, and are developing and plan to develop compounds to treat many of these disorders.

**Table of Contents**

**Figure 1: Our GPCR Discovery Platform**

Figure 1 depicts our in-house discovery platform, which involves target discovery, compound discovery and preclinical development. We first identify those GPCRs with favorable profiles and eliminate the corresponding gene in mice. These knock-out mice are then evaluated through a battery of tests to identify GPCRs linked to CNS disorders. GPCRs of interest are subjected to assay development and high-throughput screening with small molecule libraries to identify compounds as potential clinical candidates. Identified compounds are then optimized in order to select clinical candidates.

Under the terms of our Exclusive Technology Option Agreement with Patobios Limited dated September 4, 2008, as amended on November 10, 2009, we have the right to purchase Patobios' assets related to the CRA, including patents and other intellectual property rights, for approximately \$10.8 million CAD, of which \$7.8 million CAD is payable in cash and \$3.0 million CAD is payable in our common stock, subject to adjustment as described below. Upon signing the agreement in September 2008 we paid Patobios a \$200,000 CAD cash option fee (\$188,000 USD) for the right to test and an exclusive option to purchase the assets during the nine-month period ending June 4, 2009. On June 12, 2009, December 3, 2009 and January 12, 2010 we paid Patobios additional cash option fees of \$522,000 CAD (\$471,000 USD), \$108,000 CAD (\$103,000 US) and \$542,000 CAD (\$527,000 US), respectively, to extend the option period until December 4, 2009, January 4, 2010 and June 4, 2010, respectively. We have the option to extend the option period for an additional six months ending December 4, 2010 by paying Patobios a cash option fee of \$500,000 CAD. If during any option period we purchase these assets, the cash portion of the purchase price will be reduced by a portion of the related option fee we paid for such period based on the number of days remaining in the period.

Under the terms of the agreement with Patobios, we have the right to screen up to three sets of five orphan GPCRs using the CRA during the option period. If we de-orphanize at least three separate orphan GPCRs using the assay, we may not screen additional sets of orphan GPCRs using the CRA without Patobios consent. Under our agreement, a GPCR is de-orphanized when we identify a set of molecules, or ligands, that bind to an orphan GPCR and meet specific potency and selectivity criteria.

In addition, if we de-orphanize at least one orphan GPCRs using the CRA:

We will be required to pay Patobios a \$500,000 CAD de-orphanization milestone payment, which will be credited in full against the cash portion of the asset purchase price should we exercise our option to purchase Patobios' assets related to the CRA;

## **Table of Contents**

We may license, partner or assign therapeutic development and/or commercialization rights associated with up to three de-orphanized orphan GPCRs to third parties, or the Third-Party Licenses, subject to Patobios approval of the scope of such Third Party Licenses (Third Party Licenses for any additional de-orphanized orphan GPCRs would require prior approval from Patobios);

If we grant any Third-Party Licenses, then until the agreement with Patobios is terminated or we purchase the assets, whichever occurs first, we are required to pay Patobios 60% of any license proceeds that we receive from such Third-Party Licenses, subject to certain exceptions, which amounts would be credited in full against the purchase price of the assets related to the CRA;

If our agreement with Patobios is terminated before we purchase the CRA assets, thereafter we will share equally with Patobios any proceeds from Third-Party Licenses;

Patobios may require us to purchase the CRA assets for the approximately \$10.8 million CAD purchase price, provided that we will not be required to purchase the assets until the sum of the following items is at least equal to \$5.135 million CAD: (a) the amount we have paid to Patobios from the Third-Party Licenses, (b) the amount of any government or non-profit funding that we have received and that is specifically allocated for the purchase of the assets and (c) the \$500,000 CAD de-orphanization milestone payment;

We may not terminate the agreement for convenience during an option period for which we have elected to pay an option fee and none of the option fees paid will be refundable to us except in case of a breach of the agreement by Patobios; and

If by June 4, 2010 we have de-orphanized at least one orphan GPCR but have not purchased the CRA assets, we will be required to extend the option period until December 4, 2010 at a cost of \$500,000 CAD.

## **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 build an internal sales and marketing organization to market OMS103HP in North America and rely on third parties to perform these services for us in markets outside of North America. 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 for 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 laws and regulations. We anticipate that we will rely on contract manufacturers to develop and

**Table of Contents**

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 registration 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 believe that sufficient quantities of lyophilized OMS103HP have been manufactured to support the ongoing Phase 3 clinical program through completion. 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 are currently conducting a nonclinical study to demonstrate 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 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, although we intend to do so prior to the commercial launch of OMS103HP. Given the large amount of these

## **Table of Contents**

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 contracted with Althea Technologies, Inc. for the manufacture, release testing, and stability testing of clinical supplies of OMS302 and OMS201 at negotiated prices. These agreements end one year following Althea's satisfactory completion of all services required under the agreements, although we may terminate the agreements at any time upon notice to Althea. The APIs included in OMS302 and OMS201 are available from commercial suppliers.

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.

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;

**Table of Contents**

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**

We have made a significant investment in the development of a patent portfolio to protect our technologies and programs, and intend to continue to do so. As of March 1, 2010, we owned a total of 21 issued or allowed patents and 31 pending patent applications in the United States and 73 issued or allowed patents and 98 pending patent applications in commercially significant foreign markets directed to therapeutic compositions and methods related to our PharmacoSurgery platform and preclinical development programs. As of March 1, 2010, we also held worldwide exclusive licenses to two pending U.S. Patent applications, an issued foreign patent and two pending foreign patent applications. 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 1, 2010, our patent portfolio included 14 U.S. and 42 foreign issued or allowed patents, and eight U.S. and 26 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, which potentially may be extended as a result of adjustment of patent terms resulting from USPTO delays. We will 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 and further strengthened our initial patent position

with a series of patent applications directed to what we believe are the key physiological and technical elements of selected surgical procedures, and to the therapeutic classes that provide opportunities to improve clinical benefit during and after these procedures. Accordingly, our pending PharmacoSurgery patent applications are directed to combinations of agents, drawn from therapeutic classes such as pain and inflammation inhibitory agents, spasm inhibitory agents, vasoconstrictive agents, mydriatic agents and agents that reduce intraocular pressure, that are preferred for use in arthroscopic procedures, ophthalmologic procedures including intraocular procedures, and urologic procedures including ureteroscopy, for OMS103HP,

**Table of Contents**

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 1, 2010, we owned four issued U.S. Patents, two pending U.S. Patent Applications, and 12 issued patents and 8 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 1, 2010, we owned two pending U.S. Patent Applications and two issued patents and 10 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 1, 2010, we owned three issued U.S. Patents, two pending U.S. Patent Applications, and an additional 10 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.

*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 and from its collaborator, Medical Research Council at Oxford University. These licenses include what we believe to be each institution's joint ownership rights in patent applications and patents related to MASP-2 antibodies initially filed by researchers at Aarhus Universitet, Denmark. As of March 1, 2010, we exclusively controlled five pending U.S. Patent Applications and 21 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.

*Addiction Program.* As of March 1, 2010, we owned three pending U.S. Patent Applications and 11 pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, India, Japan, Mexico, New Zealand, Russia and South Korea) directed to the recently discovered link between PPAR and addictive disorders.

*PDE10 Program.* Medicinal chemistry developments in our PDE10 program have resulted in two pending U.S., one pending European and two pending PCT Patent Applications as of March 1, 2010 that claim what we believe to be novel chemical structures, as well as claiming the use of a broader set, or genus, of chemical structures as inhibitors of PDE10 for the treatment of schizophrenia and other psychotic disorders.

*PDE7 Program.* As of March 1, 2010, we owned two pending U.S. Patent Applications and ten pending patent applications in foreign markets (Australia, Brazil, Canada, China, Europe, India,

**Table of Contents**

Japan, Mexico, New Zealand and Russia) directed to the previously unknown link between PDE7 and movement disorders.

*GPCR Program.* As of March 1, 2010, we owned one issued U.S. Patent, three pending U.S. Patent Applications, and two issued patents and two pending patent applications in foreign markets (Australia, Europe and Japan), which are directed to previously unknown links between specific molecular targets in the brain and a series of CNS disorders, and to research tools that are used in our GPCR program.

All of our employees enter into our standard Employee Proprietary Information and Inventions Agreement, which includes confidentiality provisions and provides us ownership of all inventions and other intellectual property made by our employees that pertain to our business or that relate to our employees' work for us or result 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.

*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.

*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 and from its collaborator, Medical Research Council at Oxford University, or MRC. Concurrent with execution of the license agreement with the University of Leicester, two provisional US Patent Applications directed to methods of treating conditions associated with complement activation by inhibiting MASP-2 or a related protein, and a British application directed to MASP-2 knock-out mice, were filed. Exclusive licenses to these three initial patent applications were conveyed to us by





## **Table of Contents**

the University of Leicester license agreement. For a more detailed description of these licenses, see [Business Our Product Candidates and Development Programs MASP-2 Program](#).

*Addiction Program.* We acquired the patent applications and related intellectual property rights for our Addiction 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 Addiction Program](#).

*PDE10, PDE7 and GPCR Programs.* We acquired our PDE10, PDE7 and GPCR programs and some of our related patents and other intellectual property rights as a result of our acquisition of nura, inc. in August 2006 for an aggregate purchase price of \$14.4 million. We hold an exclusive license to certain PDE7 inhibitors claimed in patents and pending patent applications owned by Asubio Pharma Co., Ltd. for use in the treatment of movement disorders and other specified indications. We also hold an exclusive option to purchase the CRA for our GPCR program from Patobios Limited for approximately \$10.8 million CAD. For a more detailed description of our agreement with Asubio, see [Business Our Product Candidates and Development Programs PDE7 Program](#), and for a more detailed description of our agreement with Patobios, see [Business Our Product Candidates and Development Programs GPCR 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

## **Table of Contents**

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.

*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.

## **Table of Contents**

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 \$16.9 million, \$17.9 million and \$15.9 million in 2009, 2008 and 2007, respectively.

## **Employees**

As of March 31, 2010, we had 67 full-time employees, 51 of whom are in research and development and 16 of whom are in finance, legal and administration, including three with M.D.s and 18 with Ph.D.s. None of our employees is represented by a labor union and we consider our employee relations to be good.

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

The following table provides information regarding our executive officers and key employees as of March 31, 2010:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
<i>Executive Officers:</i>		
Gregory A. Demopulos, M.D.	51	President, Chief Executive Officer and Chairman of the Board of Directors
Marcia S. Kelbon, J.D.	50	Vice President, Patent and General Counsel and Secretary
<i>Key Employees:</i>		
Timothy M. Duffy	49	Vice President, Business Development
George A. Gaitanaris, M.D., Ph.D.	53	Vice President, Science
Wayne R. Gombotz, Ph.D.	50	Vice President, Pharmaceutical Operations
J. Greg Perkins, Ph.D.	65	Vice President, Regulatory Affairs and Quality Systems
Clark E. Tedford, Ph.D.	51	Vice President, Research
David R. Toll	42	Director of Finance and Controller
J. Steven Whitaker, M.D., J.D.	54	Vice President, Clinical Development and Chief Medical Officer

*Gregory A. Demopulos, 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. Demopulos completed his residency in orthopedic surgery at Stanford University and his fellowship training at Duke University. Dr. Demopulos currently serves on the board of directors of Onconome, Inc., a privately held company developing biomarkers for early cancer detection. Dr. Demopulos received his M.D. from the Stanford University School of Medicine and his B.S. from Stanford University. Dr. Demopulos is the brother of Peter A. Demopulos, M.D., a member of our board of directors.

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

*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



## **Table of Contents**

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.

*Clark E. Tedford, Ph.D.* has served as our vice president, research since July 2003. From 2002 to 2003, Dr. Tedford served as president and chief executive officer of Solentix, Inc., a company that developed treatments for disorders of the central nervous system and inflammatory diseases. From 1993 to 2003, Dr. Tedford worked for Gliatech Inc., a company that developed biosurgery and pharmaceutical products, most recently as executive vice president, research and development. Prior to Gliatech, Dr. Tedford served in various positions at Schering Plough. Dr. Tedford received his Ph.D. in pharmacology and his B.A. from the University of Iowa and completed his post-doctoral work in the Department of Pharmacology at the Loyola University Medical School.

*David R. Toll* has served as our director of finance and controller since January 2006. He previously served as our controller and operations manager beginning in November 2000. From 1998 to 2000, Mr. Toll 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.

## **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.

**Table of Contents**

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, estimate, project, predict, 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 ongoing Phase 3 clinical trials of OMS103HP during the second half of 2010;

our ability to market OMS103HP by 2011, at the earliest;

our ability to initiate a second Phase 2 clinical trial for OMS302 in patients undergoing cataract surgery in mid-2010;

our ability to complete the Phase 1/Phase 2 clinical trial of OMS201 in patients undergoing ureteroscopic removal or ureteral or renal stones in the second quarter of 2010;

our expectation that enrollment in a Phase 2 clinical study in our Addiction program will begin in the first half of 2010;

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

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;

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 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

**Table of Contents**

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.

**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 and Operations**

**Our success largely depends on the success of our lead PharmacoSurgery<sup>tm</sup> 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 clinical development and commercialization of our lead product candidate, OMS103HP, for use during arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery as well as arthroscopic meniscectomy surgery. We have not yet obtained regulatory approval to market this product candidate for ACL reconstruction surgery, arthroscopic 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. We are currently conducting a Phase 3 clinical program of OMS103HP for ACL reconstruction and expect to release the results during the second half of 2010. There can be no assurance that the data will be positive. Even if the data is positive, the FDA may decide that our 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 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 2011 at the earliest.

**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 are finalizing preparations to initiate a second Phase 2 clinical trial for OMS302 to assess the effect of the mydriatic API alone and in

**Table of Contents**

combination with varying concentrations of the anti-inflammatory API in a full-factorial design. We are also conducting a Phase 1/Phase 2 clinical trial evaluating the efficacy, safety and systemic absorption of OMS201 when used during ureteroscopy for removal of ureteral or renal stones. 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.

**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 \$21.1 million, \$23.8 million and \$23.1 million for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009, we had an accumulated deficit of approximately \$118.3 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.

**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. The FDA has not approved any of our 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



## **Table of Contents**

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.

**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:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

**Table of Contents**

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.

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:

complete the Phase 3 clinical trials of OMS103HP for use in arthroscopic ACL reconstruction surgery and begin related commercialization activities;

initiate, conduct and complete the Phase 3 clinical trials of OMS103HP for use in arthroscopic 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;

continue our research and development;

make milestone payments to our collaborators;

make principal and interest payments due under our debt facility with BlueCrest Venture Finance Master Fund Limited, or BlueCrest;

initiate and conduct clinical trials for other product candidates; and

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

In addition, if we elect under our Exclusive Technology Option Agreement with Patobios Limited to purchase assets for use in our GPCR program, we will be required to pay Patobios approximately \$10.8 million CAD, of which approximately \$7.8 million CAD is payable in cash and the remaining is payable in shares of our common stock.

Our clinical trials for OMS103HP may be delayed 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 beyond what we raised in our October 2009 IPO to complete the clinical development and commercialization of OMS103HP and to decrease spending on our other clinical and preclinical development programs. Although we plan to seek to raise additional funding, we have no commitments for additional

## **Table of Contents**

funding and cannot be certain that it will be available on acceptable terms, if at all. Continued disruptions in the global equity and credit markets may further limit our ability to access capital. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience significant dilution. Any debt financing, if available, may restrict our operations similar to the description in the following risk factor. 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.

### **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 2008 we borrowed \$17.0 million pursuant to the terms of a loan and security agreement with BlueCrest and pledged substantially all of our assets, other than intellectual property, as collateral for this loan. Our agreement with BlueCrest 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 BlueCrest 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, BlueCrest 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, BlueCrest'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 BlueCrest 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 BlueCrest's declaration through negotiation or litigation. Any declaration by BlueCrest 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;

**Table of Contents**

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;

publicity concerning our products or competing products and treatments; and

our ability to obtain sufficient third-party insurance coverage.

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.

**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 have no experience in the sales, marketing and distribution of biopharmaceutical products. Developing an internal sales force is expensive and time-consuming and should be commenced 12 to 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



**Table of Contents**

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 currently intend to rely solely on third parties to manufacture clinical and commercial supplies of all of our product candidates.**

We currently 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 of 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 will be able to do so on commercially reasonable terms. Qualification of any other facility to manufacture lyophilized 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 are currently conducting a nonclinical study to demonstrate 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

## **Table of Contents**

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 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 Asubio Pharma 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.

**Table of Contents**

**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 and from the UK Medical Research Council, or MRC. The continued maintenance of these agreements requires us to undertake development activities if and when a clinical candidate has been selected and, if regulatory approval for marketing is obtained, to pay royalties to the University of Leicester and MRC upon commercialization of a MASP-2 product candidate. 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 MASP-2 program could be jeopardized by third-party patent rights.**

Our MASP-2 program is based in part on the results of research conducted by collaborators at MRC, the University of Leicester and Aarhus Universitet, and on intellectual property rights that we licensed on a worldwide exclusive basis from the University of Leicester and from MRC stemming from that collaborative research and from subsequent research performed by the University of Leicester and by MRC. Researchers at Aarhus Universitet have obtained a U.S. Patent that claims antibodies that bind MASP-2, and have filed other patents and patent applications related to MASP-2. While we do not hold any direct license from Aarhus Universitet or its researchers, our license from MRC includes MRC's joint ownership interest in this U.S. Patent claiming antibodies that bind MASP-2, which joint ownership interest arises from an MRC employee having been added as a named inventor in this patent by the U.S. Patent and Trademark Office, or USPTO. We also believe that we hold lawful rights to other patents and patent applications related to MASP-2 filed by researchers at Aarhus Universitet by virtue of our licenses with MRC and the University of Leicester. Our ability to commercialize any MASP-2 antibody product candidate depends on the exclusive licenses we hold from MRC and the University of Leicester to at least joint ownership interest in the patents and patent applications filed by researchers at Aarhus Universitet. We have been in discussions with parties related to the Aarhus Universitet researchers regarding the terms of a potential additional license that could, if we deemed it to be advantageous, expand our position with respect to these patents and patent applications from exclusive licenses of at least joint ownership rights to exclusive licenses of all ownership rights. We cannot be certain that we would be able to reach agreement on favorable terms, if any, of any such additional license, if determined to be advantageous, or that the Aarhus Universitet researchers or the parties related to them will not contest our licensed rights to these patents and patent applications, or that they will not seek through legal action to block the commercialization of any antibody product candidate from our MASP-2 program based on these or other patent applications that they filed. Perfecting, asserting or defending our rights to this intellectual property may be costly and time-consuming and, if unsuccessful, may limit our ability to pursue the development and commercialization of product candidates from our MASP-2 program.

**Our ability to pursue the development and commercialization of product candidates from our MASP-2 program depends on third-party antibody developers and manufacturers.**

Any product candidates from our MASP-2 program would be antibodies and we do not have the internal capability to sequence, hybridize or clone antibodies or to produce antibodies for use in clinical trials or on a commercial scale. We have entered into development agreements with Affitech AS and North Coast Biologics for the development of MASP-2 antibodies; however, we do not have agreements in place with antibody manufacturers to manufacture clinical or commercial quantities of MASP-2 antibodies 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 antibody manufacturers. If we are unable to obtain clinical supplies of MASP-2 antibody product candidates, clinical trials or the development of any such product candidate 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.

## **Table of Contents**

### **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 MASP-2, PDE10, PDE7 and GPCR programs, must successfully complete preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before entering clinical trials. Many pharmaceutical and biological 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 druggable 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.

### **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. 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 upon 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



**Table of Contents**

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. 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 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 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;

it is possible that none of our pending patent applications will result in issued patents or, if issued, these patents may not be sufficient to protect our technology or provide us with a basis for commercially viable products and may not 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.

**Table of Contents**

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

If we choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe the patents.

Further, a third party may claim that we or our contract manufacturers are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in the alleged infringing activity, including making, using or selling our 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 OMS103HP, OMS302, OMS201, MASP-2, Addiction, PDE10, PDE7 and GPCR programs, these searches may not have identified all third-party patents relevant to these programs. 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. For example, we are aware of a U.S. Patent that claims antibodies that bind MASP-2 and other patents and patent applications related to MASP-2 held by researchers at Aarhus Universitet that are described above in more detail in these Risk Factors. Our ability to commercialize any MASP-2 antibody product candidate depends on the exclusive licenses we hold from MRC and the University of Leicester to at least joint ownership interest in the patents and patent applications filed by researchers at Aarhus Universitet.

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.

**Table of Contents**

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

Our research operations produce hazardous waste products, which include chemicals and radioactive and biological materials. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply with applicable legal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. We generally contract with third parties for the disposal of such substances and store our low-level radioactive waste at our facilities until the materials are no longer considered radioactive. We may be required to incur further costs to comply with current or future environmental and safety regulations. In addition, although we carry insurance, in the event of accidental contamination or injury from these materials, we could be held liable for any damages that result and any such liability could exceed our insurance coverage and other resources.

**The loss of members of our management team could substantially disrupt our business operations.**

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies except for on the life of Gregory Demopoulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, could delay 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

**Table of Contents**

and the audit committee findings; the NIH confirmed to us in writing that it was satisfied with our handling of these grant matters.

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. Although we have been advised by outside employment and corporate counsel that we have meritorious defenses to Mr. Klein's allegations, and we intend to defend 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. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. 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 not currently required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, and are therefore not required to make an assessment of the effectiveness of our internal controls over financial reporting. Further, our independent registered public accounting firm has not been engaged to express, nor has it expressed, an opinion on the effectiveness of our internal controls over financial reporting. We will be required under Section 404 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 fiscal years ending after December 31, 2009. 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 not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, 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 develop and 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



**Table of Contents**

otherwise 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 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. 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 testing and surveillance to monitor the safety or efficacy of the product candidate. Later

**Table of Contents**

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;

fines;

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 upon 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.

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. There may

## **Table of Contents**

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 \$5.27 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 trials for OMS103HP for use in ACL reconstruction surgery, our ongoing Phase 2 clinical trial for OMS302, our ongoing Phase 1/Phase 2 clinical trial for OMS201, and our ongoing Phase 2 clinical trial for our Addiction program;

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

- 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;

**Table of Contents**

third-party coverage and reimbursement policies;

additions or departures of key personnel;

commencement of, or our involvement in, litigation;

our ability to meet our repayment and other obligations under our debt facility with BlueCrest, pursuant to which we have borrowed \$17.0 million;

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.

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.

**Future sales of shares by existing shareholders could cause our stock price to decline.**

Approximately 14.5 million shares of our common stock will become available for sale by our shareholders upon the expiration of lock-up agreements in April 2010. If these shareholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up period lapses, the trading price of our common stock could decline. In addition, approximately 5.1 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, the lock-up agreements and Rules 144 and 701 under the Securities Act, as applicable. 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



**Table of Contents**

or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

**Our management has broad discretion over the use of the net proceeds we received from our initial public offering and may not use the net proceeds in ways that increase the value of our stock price.**

We have broad discretion over the use of the net proceeds we received from our initial public offering and we could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

**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 17,000 square feet for our principal administrative facility under leases that expire August 31, 2011, and we lease approximately 25,300 square feet for our research and development facility, which includes a modern vivarium, under a lease that expires September 30, 2011. Our two 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 \$2.1 million. We believe that the facilities we lease currently are sufficient for our anticipated near-term needs.

**ITEM 3. LEGAL PROCEEDINGS**

On September 29, 2008 we filed a complaint in U.S. District Court for the Western District of Washington, against Scottish Biomedical, Ltd., a United Kingdom private limited company, related to contract laboratory services provided by Scottish Biomedical for our PDE10 and PDE7 programs. In our complaint, we alleged that Scottish Biomedical breached our contract laboratory services agreement, committed fraud and misrepresentations and fraudulent concealment and violated the Washington Consumer Protection Act. Our complaint sought unspecified damages resulting from our having to re-perform certain services provided by Scottish Biomedical and for losses we suffered as a result of delays to the advancement of our programs. On December 3, 2009, we entered into a settlement and release agreement with Scottish Biomedical under which we released all of our claims against Scottish Biomedical and agreed to dismiss our complaint in exchange for structured settlement payments covering past research costs. This is included in accounts receivable and other long-term assets.

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

**Table of Contents**

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. We intend to vigorously defend ourselves against Mr. Klein's claims and to seek, among other things, our attorneys' fees and costs incurred in defending this action.

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 these grant matters. 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>2009</b>	<b>High</b>	<b>Low</b>
4 <sup>th</sup> Quarter (October 8, 2009 through December 31, 2009)	\$ 9.49	\$ 5.27

**Holders**

As of March 24, 2010, there were approximately 706 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 BlueCrest Venture Finance Master Fund Limited we have agreed not to pay any dividends so long as we have any outstanding obligations under the agreement. We expect to retain all available funds and future earnings, if any, to fund the development and growth of our business and we do not anticipate paying any cash dividends in the foreseeable future.

**Stock Performance Graph**

The following graph compares the cumulative total shareholder return for our common stock, the NASDAQ Biotechnology Index and the NASDAQ Composite Index for the period beginning October 8, 2009 (the date of our initial public offering) and ending December 31, 2009. 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.

**Table of Contents**

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.

**Recent Sales of Unregistered Securities**

- (1) From January 1, 2009 to June 9, 2009, we granted to employees and consultants option awards to purchase 112,496 shares of common stock with per share exercise prices ranging from \$12.41 to \$12.47. We issued these unregistered securities in reliance on Rule 701 promulgated by the Securities and Exchange Commission under the Securities Act of 1933, as amended, as transactions by an issuer pursuant to a compensatory benefit plan.
- (2) From January 1, 2009 to December 31, 2009, we issued 12,461 shares of common stock to certain of our option holders upon exercise of option awards for an aggregate purchase price of \$27,550. We issued these unregistered securities in reliance on Rule 701 promulgated by the Securities and Exchange Commission under the Securities Act of 1933, as amended, as transactions by an issuer pursuant to a compensatory benefit plan.
- (3) On October 15, 2009 we issued 15,306 shares of common stock to one of our option holders upon exercise of option awards in exchange for the surrender of 2,134 shares of our common stock with a market value as of the date of exercise of \$15,000, which was equal to the exercise price of such option awards. We issued these unregistered securities in reliance on Rule 701 promulgated by the Securities and Exchange Commission under the Securities Act of 1933, as amended, as transactions by an issuer pursuant to a compensatory benefit plan.
- (4) On February 18, 2009 we issued 122,449 shares of our Series E convertible preferred stock for an aggregate purchase price of \$1.2 million to an accredited investor. These shares of Series E convertible preferred stock automatically converted into common stock upon the closing of our initial public offering. We issued these unregistered securities in reliance on Section 4(2) of the Securities Act of 1933, as amended, as a transaction not involving a public offering.

**Purchase of Equity Securities by the Issuer and Affiliated Purchasers**

From October 1, 2009 to December 31, 2009, we repurchased the following shares of our common stock:

<b>Period</b>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Program</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
10/1/09 - 10/31/09	2,134(1)	\$ 7.03(1)	NA	NA
11/1/09 - 11/30/09	0	0	NA	NA
12/1/09 - 12/31/09	0	0	NA	NA

- (1) Represents shares of common stock surrendered to us as payment for the exercise price of option awards. The average price paid per share is the closing price of our common stock on the date these shares of common

stock were surrendered.

**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, 2009
	2009	2008	2007	2006	2005	
	(in thousands, except share data)					
<b>Consolidated Statements of Operations Data:</b>						
Grant revenue	\$ 1,444	\$ 1,170	\$ 1,923	\$ 200	\$	\$ 4,837
Operating expenses:						
Research and development	16,929	17,850	15,922	9,637	5,803	79,163
Acquired in-process research and development				10,891		10,981
General and administrative	5,273	7,845	10,398	3,625	1,904	37,756
Total operating expenses	22,202	25,695	26,320	24,153	7,707	127,810
Loss from operations	(20,758)	(24,525)	(24,397)	(23,953)	(7,707)	(122,973)
Investment income	214	661	1,582	1,088	333	5,377
Interest expense	(2,202)	(335)	(151)	(91)		(2,831)
Other income (expense)	1,657	372	(125)	179	8	(2,091)
Net Loss	\$ (21,089)	\$ (23,827)	\$ (23,091)	\$ (22,777)	\$ (7,366)	\$ (118,336)
Basic and diluted net loss per common share	\$ (2.92)	\$ (8.26)	\$ (10.65)	\$ (12.08)	\$ (4.16)	
Denominator for basic and diluted net loss	7,218,915	2,883,522	2,167,500	1,884,925	1,769,830	

per common share

	<b>As of December 31,</b>				
	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	60,305	19,982	24,082	35,885	12,372
Working capital (deficit)	49,574	(3,083)	16,526	32,277	10,672
Total assets	62,062	21,681	27,162	38,432	13,109
Total notes payable	12,758	16,674	1,010	2,015	0
Preferred stock warrant liability		1,780	1,562	1,037	483
Convertible preferred stock		89,168	89,168	85,742	40,888
Deficit accumulated in the development stage	(118,336)	(97,247)	(73,420)	(50,329)	(27,553)
Total shareholders' equity (deficit)	43,145	(91,166)	(69,941)	(53,363)	(29,743)



**Table of Contents****ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis should be read in conjunction with our audited annual consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. For further information regarding forward-looking statements, please refer to the special note regarding forward-looking statements at the 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 focused on inflammation 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 five ongoing clinical development programs, including four from our PharmacoSurgery platform and one from our Addiction program. Our most advanced clinical development program is in Phase 3 clinical trials. In addition, we have leveraged our expertise in inflammation and the central nervous system to build a deep and diverse pipeline of preclinical programs targeting large markets 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, expected to include a total of approximately 1,040 patients, evaluating OMS103HP's safety and ability to improve postoperative joint function and reduce pain following arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery. The second program is evaluating OMS103HP's safety and ability to reduce pain and improve postoperative joint function following arthroscopic meniscectomy surgery. We expect to release the results from our ongoing Phase 3 clinical program for ACL reconstruction surgery during the second half of 2010. 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 recently completed a Phase 1/Phase 2 clinical trial that evaluated the efficacy and safety of OMS302 added to standard irrigation solution and delivered to patients undergoing cataract surgery as well as a Phase 2 concentration-ranging clinical trial of the mydriatic API contained in OMS302 as a mydriasis induction agent. We are finalizing preparations to initiate a second Phase 2 clinical trial for OMS302 to assess the effect of the previously determined concentration of the mydriatic API alone and in combination with varying concentrations of the anti-inflammatory API in a full-factorial design. A Phase 1/Phase 2 clinical trial of OMS201 is underway in patients undergoing ureteroscopic removal of ureteral or renal stones.

In addition to our PharmacoSurgery platform, we have a deep and diverse pipeline of additional product development programs targeting large market opportunities in inflammation and the CNS covered by a broad intellectual property portfolio. In our Addiction program, we are developing proprietary compositions that include peroxisome proliferator-activated receptor gamma, or PPAR , agonists for the treatment and

## **Table of Contents**

prevention of addiction to substances of abuse, which may include opioids, nicotine, alcohol and amphetamines, as well as other compulsive behaviors. In January 2010 we announced that the National Institute on Drug Abuse has agreed to fund substantially all of the costs of a Phase 2 clinical study to evaluate a PPAR agonist in the treatment of addiction to opioids.

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. Our PDE7 program is based on our demonstration of a previously unknown link between PDE7 and any movement disorder, such as Parkinson's disease and Restless Legs Syndrome, and we are developing proprietary compounds for the treatment of these and other movement disorders. In our GPCR program, we believe that we have the capability 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 incurred significant losses since our inception. As of December 31, 2009, our accumulated deficit was \$118.3 million and total shareholders' equity was \$43.1 million. We recognized net losses of \$21.1 million, \$23.8 million and \$23.1 million for the years ended December 31, 2009, 2008 and 2007, 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 2009, 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.

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 \$4.8 million of revenue from inception through December 31, 2009, consisting of grant funding from third parties. 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 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 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.

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

**Table of Contents**

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 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 since inception to December 31, 2009 were \$79.2 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:

	<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
	<b>(in thousands)</b>		
<b>Clinical Research and Development</b>			
Salaries, benefits, and related costs	\$ 3,666	\$ 3,521	\$ 2,944
Clinical trials	2,270	3,525	3,630
Manufacturing services, consulting, laboratory supplies, and other costs	3,043	2,080	1,943
Other costs	1,106	1,049	633
Stock-based compensation	502	590	280
<b>Total Clinical Research and Development Expenses</b>	<b>10,587</b>	<b>10,765</b>	<b>9,430</b>
<b>Preclinical Research and Development</b>			
Salaries, benefits, and related costs	2,506	2,572	2,315
Research and preclinical studies, consulting, laboratory supplies, and other costs	1,974	2,774	2,566
Other costs	1,485	1,346	1,412
Stock-based compensation	377	393	199
<b>Total Preclinical Research and Development Expenses</b>	<b>6,342</b>	<b>7,085</b>	<b>6,492</b>
<b>Total Research and Development Expenses</b>	<b>\$ 16,929</b>	<b>\$ 17,850</b>	<b>\$ 15,922</b>

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 as well as the availability of cash to fund the programs. 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.

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 2011, if at all. Because of the factors above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

**Table of Contents**

*General and Administrative Expenses*

General and administrative expenses consist principally of salaries and related costs for personnel in executive, legal, finance, accounting, 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.

*Interest Expense*

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

*Other Income (Expense)*

Other income (expense) consists primarily of 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, 2009, we had federal net operating loss carryforwards and research and development tax credit carryforwards of approximately \$91.8 million and \$2.6 million, respectively. Our net operating loss and research and development tax credit carryforwards began to expire in 2009 and should continue to expire through 2029 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;

preferred stock warrant liability; and

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.



**Table of Contents***Revenue Recognition*

Our revenue since inception relates to grant funding from third parties. We recognize grant funding as revenue when the related qualified research and development expenses are incurred up to the limit of the approved funding amounts.

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 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.

*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 accrual; these changes in estimates may result in understated or overstated expenses at a given point in time. To date, our estimates have not differed significantly from actual costs. Internal research and development expenses are expensed as incurred. Third-party research and development expenses are expensed at the earlier of when the contracted work has been performed or as upfront and milestone payments are made.

*Stock-Based Compensation*

We account for stock-based compensation under applicable accounting standards using the prospective method, 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.

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:

	<b>2009</b>	<b>December 31, 2008</b>	<b>2007</b>
Expected volatility	71%-78%	60%	60%
Expected term (in years)	6.08	6.08	6.00-6.08
Risk-free interest rate	2.13%-2.72%	2.8%-3.40%	3.78%-4.78%
Expected dividend yield	0%	0%	0%

*Expected Volatility.* 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.

**Table of Contents**

*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.

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

Stock options granted to non-employees are accounted for using the fair value approach. The fair value of non-employee option grants are estimated using the Black-Scholes option-pricing model and are re-measured over the vesting term as earned. The estimated fair value is charged to expense over the applicable service period. During the year ended December 31, 2007, we granted 80,475 options to non-employees to purchase shares of common stock. During the years ended December 31, 2009 and 2008 no options were granted to non-employees.

*Stock Options and Note Receivable from Related Party.* In conjunction with the exercise of certain stock options by Gregory A. Demopoulos, M.D., our president, chief executive officer and chairman of the board of directors, we received promissory notes from Dr. Demopoulos totaling \$239,000 between 2002 and 2005. The promissory notes accrued interest at rates ranging from 3% to 6.25% and were secured by pledges of the underlying common stock. Based on the terms of the notes, the stock options were subject to variable accounting whereby changes in the estimated fair value of the underlying option is reported as an increase or decrease, as applicable, in stock-based compensation expense (credit) until such time that the notes were repaid. Stock-based compensation expense (credit) related to these notes and common stock was \$5.0 million and \$361,000 for the years ended December 31, 2007 and 2006, respectively. The notes and accrued interest were repaid in full in December 2007.

*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. Such fair values were estimated using the Black-Scholes option-pricing model and an estimated term equal to each warrant's contractual life. The preferred stock warrant liability was reclassified to equity upon the completion of our IPO in October 2009 with the conversion of all of the convertible preferred stock warrants to common stock warrants.

*Fair Value Measurement of Financial Instruments*

Effective January 1, 2008, we adopted the fair value measurement standards for our financial assets and liabilities. Under these standards, 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. On January 1, 2009, we adopted the guidance related to nonfinancial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis. The adoption of this guidance did not have a material impact on our financial position, results of operations or cash flows.

## **Table of Contents**

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.

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.

As of December 31, 2009, our investment portfolio was made up of cash and cash equivalents of \$1.0 million, money-market funds of \$56.5, and adjustable rate securities, issued by, or fully collateralized by, the U.S. government or U.S. government-sponsored entities, of \$2.9 million. 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.

We believe that the values assigned to our available-for-sale securities and mortgage backed securities as of December 31, 2009, 2008 and 2007 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 as of December 31, 2009 were recoverable in all material respects. In 2009, the U.S. economy continued to be adversely affected by tightening in the credit markets and volatility in capital markets. Interest rates on U.S. treasury instruments declined considerably during this crisis while other interest rates fluctuated in excess of historical norms. Continuing distress in the economic environment could ultimately result in other-than-temporary impairments of the carrying values of our available-for-sale securities and/or a material adverse impact on the carrying values of our financial instruments.

## **Results of Operations**

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

*Revenue.* Revenue was \$1.4 million in 2009 compared with \$1.2 million in 2008. The increase was primarily due to higher grant revenue recognized under our grant from The Michael J. Fox Foundation 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 with \$17.9 million in 2008. The decrease was due primarily to a reduction in contract service costs associated with several of our clinical and preclinical programs and in clinical trial expenses due to the prior completion of enrollment in the Phase 2 clinical study of OMS103HP for arthroscopic meniscectomy surgery, and was partially offset by an increase

of \$903,000 in technology acquisition option fees related to our right to purchase assets from Patobios Limited for use in our GPCR program.

**Table of Contents**

*General and Administrative Expenses.* General and administrative expenses were \$5.3 million in 2009 compared with \$7.8 million in 2008. The decrease was due primarily 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 with \$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 with \$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.

*Comparison of Years Ended December 31, 2008 and December 31, 2007*

*Revenue.* Revenue was \$1.2 million in 2008 compared with \$1.9 million in 2007. Revenue in 2008 and 2007 represents grant funding from third parties related to our MASP-2, PDE10 and GPCR programs. The decrease was primarily due to approximately \$300,000 less recognized under a grant for our PDE10 program from The Stanley Medical Research Institute and approximately \$445,000 less recognized on an NIH grant in 2008 compared to 2007, as the research related to each grant award was coming to a completion in 2008.

*Research and Development Expenses.* Research and development expenses were \$17.9 million in 2008 compared with \$15.9 million in 2007. The increase was due primarily to additional personnel, stock-based compensation expense and facility and research costs, and increased preclinical research study costs associated with our MASP-2 and PDE10 programs.

*General and Administrative Expenses.* General and administrative expenses were \$7.8 million in 2008 compared with \$10.4 million in 2007. The decrease was due primarily to higher stock-based compensation in 2007. Stock-based compensation for the years ended December 31, 2008 and 2007 were \$1.3 million and \$5.6 million, respectively. The higher stock-based compensation in 2007 relates primarily to related-party notes receivable that were treated as variable option awards through their repayment in December 2007. An increase in the fair value of our common stock during 2007 resulted in an increase to this expense. Excluding stock-based compensation expense, the increase in general and administrative expenses in 2008 primarily reflects the \$1.9 million non-cash write off of a portion of our deferred offering costs related to our initial public offering, additional personnel and higher patent legal costs, partially offset by a decrease in audit fees and overall professional services costs.

*Investment Income.* Investment income was \$661,000 in 2008 compared with \$1.6 million in 2007. The decrease is due to interest earned on lower average cash balances in 2008 compared to 2007.

*Interest Expense.* Interest expense was \$335,000 in 2008 compared with \$151,000 in 2007. Interest expense increased in 2008 due to our borrowings from BlueCrest. Interest expense also includes interest incurred through September 2008 on a note we assumed in connection with our acquisition of nura in 2006.

*Other Income (Expense).* Other income was \$372,000 in 2008 compared to other (expense) of \$(125,000) in 2007. The increase in other income is primarily due to income received from new sublease tenants and we recognized less expense from the revaluation of the fair value of warrants in 2008 compared to 2007.

## **Liquidity and Capital Resources**

Since inception, we have financed our operations primarily through the private placement of equity securities for proceeds totaling \$77.4 million and through a debt facility with loan proceeds totaling \$17.0 million. In October 2009, we completed our IPO and issued and sold a total of 6,820,000 shares of common stock for aggregate net proceeds of \$61.8 million.



**Table of Contents**

As of December 31, 2009, we had \$60.3 million in cash, cash equivalents and short-term investments. Our cash, cash equivalents and short-term investment balances are held in a variety of interest-bearing instruments, including money market funds and mortgage-backed securities issued by or fully collateralized by U.S. government or U.S. government-sponsored entities, high-credit-rating corporate borrowers and money market accounts. Cash in excess of immediate requirements is invested in accordance with established guidelines to preserve principal and maintain liquidity.

*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. Net cash used in each of these periods was primarily due to the net loss for the periods offset by non-cash stock-based compensation expense of \$1.5 million and \$2.3 million, respectively.

*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. In 2009, amounts used in investing were primarily from the purchase of investments compared to proceeds from the sale and maturities of investments in 2008.

*Financing Activities.* Net cash provided by financing activities was \$59.9 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 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 the loan with BlueCrest.

We cannot borrow any additional amounts under the BlueCrest agreement. Interest on amounts borrowed under the loan agreement accrues at an annual rate of 12.5%. Payments due under each tranche were interest only for the first three months, and are interest and principal thereafter for 36 months. Under the loan agreement, we must comply with affirmative and negative covenants and, if any event, condition or change occurs that has a material adverse effect (as defined in the agreement), BlueCrest may require immediate repayment of all loan amounts then currently outstanding. We have no indication that we are in default of the material adverse effect clause, and no scheduled loan payments have been accelerated as a result of this provision. We may use the proceeds of the loan for working capital, capital expenditures and general corporate purposes. Our obligations under the loan agreement are collateralized by substantially all of our assets, other than intellectual property. We may prepay the outstanding principal amount of all loans then outstanding in whole, but not in part, by providing 30 days written notice. However, a prepayment premium of 2.0% applies if the prepayment is made within 18 months after the borrowing date of the applicable tranche. If a prepayment is made more than 18 months after the date of the applicable tranche, then the prepayment premium is reduced to 1.0%. In connection with the loan and security agreement, we incurred debt issuance costs of \$122,000.

As a condition to BlueCrest making the initial \$5.0 million loan, we agreed to pay a success fee to BlueCrest in an amount up to \$400,000 should certain exit events, such as an initial public offering, occur prior to September 12, 2018. Following the completion of our initial public offering in October 2009, we paid BlueCrest a success fee in the amount of \$340,000. We have no further obligations to pay a success fee to BlueCrest.

In connection with the execution of the loan and security agreement, we issued a warrant to BlueCrest to purchase 25,213 shares of our common stock at an exercise price of \$13.48 per share. This warrant expired upon the closing of our initial public offering in October 2009 without being exercised.

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 I clinical trials totaling \$9.0 million, subject to our mutual agreement with SMRI. As of December 31, 2009, we had

received \$5.7 million from SMRI, \$1.8 million of which was recorded as revenue, \$3.2 was recorded as equity funding and \$702,000 remains in deferred revenue.

**Table of Contents**

In November 2008, we entered into an agreement with The Michael J. Fox Foundation 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. We received an advance payment of \$232,000 in December 2008 and a final installment of \$232,000 was received in July 2009.

*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 have based 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 capital requirements will depend on many factors, including:

the progress and results of our clinical trials for OMS103HP, OMS302 and OMS201;

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;

the terms and timing of payments of any collaborative or licensing agreements that we have or may establish, including pursuant to our agreements with Asubio Pharma and North Coast Biologics;

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 any of these types of transactions other than our right to acquire assets for our GPCR program from Patobios Limited for \$10.8 million CAD in cash and stock;

whether we receive grant funding for our programs; and

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

We do not anticipate generating revenue from the sale of our product candidates until 2011 at the earliest. In the absence of additional funding, 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. 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

**Table of Contents**

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, 2009.

	<b>Payments Due Within</b>				<b>Total</b>
	<b>1 Year</b>	<b>2-3 Years</b>	<b>4-5 Years</b>	<b>More than 5 Years</b>	
	<b>(in thousands)</b>				
Operating leases (1)	\$ 1,563	\$ 1,157	\$ 15	\$	\$ 2,735
License maintenance fees	5	10	10	40	65
Notes Payable (principal and interest)	6,408	8,588			14,996
<b>Total</b>	<b>\$ 7,976</b>	<b>\$ 9,755</b>	<b>\$ 25</b>	<b>\$ 40</b>	<b>\$ 17,796</b>

- (1) We are contracted to receive sublease income of \$1.6 million, \$1.1 million, \$23,000, and \$15,000 in 2010, 2011, 2012 and 2013, respectively, which is excluded from operating lease payment amounts.

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, 2009, 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 Addiction program, we may be required to pay a low single-digit percentage royalty on any net sales of a product from our Addiction 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 milestone payments of up to \$2.3 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 Asubio Pharma Co., Ltd., we have agreed to make milestone payments to Asubio 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, Asubio is entitled to receive from us a low single-digit percentage

## **Table of Contents**

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 Asubio 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.

## **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, 2009, 2008 and 2007 totaled \$5,000, \$5,000 and \$5,000, respectively, and \$450,000 for the period from inception (June 16, 1994) through December 31, 2009. In 2007, we granted Dr. Palmer an option to purchase 20,408 shares of common stock and recognized \$(15,000), \$57,000 and \$42,000 of non-cash stock compensation expense (benefit) associated with this option for the years ended December 31, 2009, 2008 and 2007, respectively, and \$84,000 for the period of inception (June 16, 1994) through December 31, 2009.

In conjunction with the exercise of certain stock options by Gregory A. Demopulos, M.D., our president, chief executive officer and chairman of the board of directors, we received promissory notes from Dr. Demopulos totaling \$239,000. The promissory notes accrued interest at rates ranging from 3% to 6.25% and were secured by pledges of the underlying common stock. Based on the terms of the notes, the notes were treated as options subject to variable accounting whereby changes in the estimated fair value of the underlying deemed options were reported as increases or decreases, as applicable, in stock-based compensation expense until such time that the notes were repaid. The notes and accrued interest were repaid in full in December 2007. For the year ended December 31, 2007 and for the period of inception (June 16, 1994) through December 31, 2009, \$5.0 million and \$5.6 million, respectively, has been recognized as stock compensation expense.

In December 2007 we approved a payment to Dr. Demopulos of \$159,000 as a tax gross-up amount related to payments that we made to him during 2007 that he used to repay his indebtedness to us in the amount of \$278,000, including principal and interest. The \$159,000 was recorded as an accrued liability as of December 31, 2007 and was subsequently paid to Dr. Demopulos in January 2008.

## **Recent Accounting Pronouncements**

In June 2009, the Financial Accounting Standards Board, or FASB, approved the Accounting Standards Codification which became the single source of authoritative United States accounting and reporting standards other than guidance issued by the Securities and Exchange Commission. The Accounting Standards Codification is a major restructuring of accounting and reporting standards; however, the codification is not intended to change existing standards. The Accounting Standards Codification is effective for interim and annual periods ending after September 15, 2009.

Effective January 1, 2009, the Emerging Issues Task Force, or EITF, issued guidance over accounting for collaborative arrangements. This guidance requires disclosure of the nature and purpose of our significant collaborative arrangements in the annual financial statements, including our rights and obligations under the arrangement, the amount and income statement classification of significant financial expenditures and commitments, and a description of accounting policies for the arrangement. This guidance requires us to apply as a change in accounting principle through retrospective application to all prior periods for all applicable collaborative arrangement existing as of the effective date. There was no impact to the results of operations or financial position upon adoption.

In April 2009, the FASB issued authoritative guidance for interim disclosures about fair value of financial instruments, which amended existing guidance. This guidance is effective for interim and annual periods ending after June 15, 2009 and expands guidance on (a) measuring the fair value of financial instruments when market activity has decreased and quoted prices may reflect distressed transactions, (b) the recognition and presentation of

other-than-temporary impairments on debt and equity securities and (c) the fair value disclosures required for financial instruments in interim reporting periods. The adoption of the fair value guidance did not impact our financial condition or results of operations.



**Table of Contents**

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.

**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, 2009, we had cash, cash equivalents and short-term investments of \$60.3 million. 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. We have invested these funds in highly liquid, investment-grade securities in accordance with our investment policy. The securities in our investment portfolio are not leveraged and are classified as available for sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates. While our investment portfolio includes mortgage-backed securities, we do not hold sub-prime mortgages. Our investments in mortgage-backed securities are issued by, or fully collateralized by, the U.S. government or U.S. government-sponsored entities.

We are exposed to potential loss due to changes in interest rates. Our principal interest rate exposure is to changes in U.S. interest rates related to our investment securities. To estimate the potential loss due to changes in interest rates, we performed a sensitivity analysis using the instantaneous adverse change in interest rates of 100 basis points across the yield curve. On this basis, we estimate the potential loss in fair value that would result from a hypothetical 1% (100 basis points) increase in interest rates to be approximately \$12,000 as of December 31, 2009.

**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, 2009. 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

**Table of Contents**

December 31, 2009, 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**

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 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include a report of our management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

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

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2010 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 2010 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 2010 Annual Meeting of Shareholders and is incorporated herein by reference.

**Table of Contents****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, 2009:

	<b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>Weighted-average Exercise Price of Outstanding Options, Warrants and Rights</b>	<b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans</b>
<i>Equity compensation plans approved by security holders:</i>			
2008 Equity Incentive Plan (1) Second Amended and Restated 1998 Stock Option Plan	201,129	\$ 10.85	1,013,256
nura, inc. 2003 Stock Option Plan	2,613,438	\$ 1.27	0
<i>Equity compensation plans not approved by security holders:</i>	2,981	\$ 10.63	0
Stock Option Grant to Gregory A. Demopulos, 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>	2,847,549	\$ 1.94	1,013,256

(1) Upon adoption of the 2008 Equity Incentive Plan, we reserved a total of 892,857 shares of our common stock for issuance thereunder plus any shares returned to the Second Amended and Restated 1998 Stock Option Plan as a result of termination of options or repurchase of shares issued pursuant to such plan, with the maximum number of shares returned equal to 3,084,848 shares. In addition, our 2008 Equity Incentive Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year equal to the least of: (1) five percent of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year; (2) 1,785,714 shares; and (3) such other amount as our board of directors may determine. On January 1, 2010, an additional 1,064,279 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.

**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 2010 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 2010 Annual Meeting of Shareholders and is incorporated herein by reference.

**Table of Contents**

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

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

**1. Financial Statements**

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

**2. Financial Statement Schedules**

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

**3. Exhibits**

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

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**OMEROS CORPORATION**

Date: March 31, 2010

By:  
/s/ Gregory A. Demopoulos, M.D.

Gregory A. Demopoulos, M.D.  
President, Chief Executive Officer  
and Chairman of the Board of Directors

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Gregory A. Demopoulos, M.D. Gregory A. Demopoulos, M.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer, Principal Accounting Officer and Principal Financial Officer)	March 31, 2010
/s/ Ray Aspiri Ray Aspiri	Director	March 31, 2010
/s/ Thomas J. Cable Thomas J. Cable	Director	March 31, 2010
/s/ Peter A. Demopoulos, M.D. Peter A. Demopoulos, M.D.	Director	March 31, 2010
/s/ Leroy E. Hood, M.D., Ph.D. Leroy E. Hood, M.D., Ph.D.	Director	March 31, 2010
/s/ Daniel K. Spiegelman Daniel K. Spiegelman	Director	March 31, 2010

/s/ Jean-Philippe Tripet

Director

March 31, 2010

Jean-Philippe Tripet

80

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**Table of Contents**

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

	<b>Page</b>
<u>REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u>	F-2
<u>CONSOLIDATED BALANCE SHEETS</u>	F-3
<u>CONSOLIDATED STATEMENTS OF OPERATIONS</u>	F-4
<u>CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY (DEFICIT)</u>	F-5
<u>CONSOLIDATED STATEMENTS OF CASH FLOWS</u>	F-10
<u>NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS</u>	F-11

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders  
Omeros Corporation

We have audited the accompanying consolidated balance sheets of Omeros Corporation (a development stage company) as of December 31, 2009 and 2008, 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, 2009 and for the period from June 16, 1994 (inception) through December 31, 2009. 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. We are not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, and for the period from June 16, 1994 (inception) through December 31, 2009, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Seattle, Washington  
March 31, 2010

**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**

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

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 820	\$ 12,726
Short-term investments	59,485	7,256
Grant and other receivables	248	207
Prepaid expenses and other current assets	111	289
Total current assets	60,664	20,478
Property and equipment, net	1,086	918
Intangible assets, net		60
Restricted cash	193	193
Other assets	119	32
Total assets	\$ 62,062	\$ 21,681
<b>Liabilities, convertible preferred stock and shareholders equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 2,620	\$ 1,229
Accrued expenses	2,837	3,764
Preferred stock warrant liability		1,780
Deferred revenue	702	232
Current portion of notes payable	4,931	16,556
Total current liabilities	11,090	23,561
Notes payable, less current portion	7,827	118
Commitments and contingencies		
Convertible preferred stock:		
Liquidation preference of \$92,084 at December 31, 2008		89,168
Shareholders equity (deficit):		
Preferred stock, par value \$0.01 per share:		
Issued and outstanding shares 0 and 11,392,057 at December 31, 2009 and 2008, respectively		
Authorized shares 20,000,000 and 13,425,919 at December 31, 2009 and 2008, respectively		
Designated convertible 0 and 13,425,919 at December 31, 2009 and 2008, respectively		
Common stock, par value \$0.01 per share:		

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Authorized shares	150,000,000 and 20,410,000	December 31, 2009 and 2008, respectively		
Issued and outstanding shares	21,285,577 and 2,951,406	December 31, 2009 and 2008, respectively		
			213	30
Additional paid-in capital			161,227	6,150
Accumulated other comprehensive income (loss)			41	(99)
Deficit accumulated during the development stage			(118,336)	(97,247)
Total shareholders' equity (deficit)			43,145	(91,166)
Total liabilities, convertible preferred stock, and shareholders' equity (deficit)			\$ 62,062	\$ 21,681

See notes to consolidated financial statements

F-3

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Table of Contents

**OMEROS CORPORATION**  
**(A Development Stage Company)**

**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(In thousands, except share and per share data)**

	Year Ended December 31,			Period from
	2009	2008	2007	June 16, 1994 (Inception) through December 31, 2009
Grant revenue	\$ 1,444	\$ 1,170	\$ 1,923	\$ 4,837
Operating expenses:				
Research and development	16,929	17,850	15,922	79,163
Acquired in-process research and development				10,891
General and administrative	5,273	7,845	10,398	37,756
Total operating expenses	22,202	25,695	26,320	127,810
Loss from operations	(20,758)	(24,525)	(24,397)	(122,973)
Investment income	214	661	1,582	5,377
Interest expense	(2,202)	(335)	(151)	(2,831)
Other income (expense)	1,657	372	(125)	2,091
Net loss	\$ (21,089)	\$ (23,827)	\$ (23,091)	\$ (118,336)
Basic and diluted net loss per common share	\$ (2.92)	\$ (8.26)	\$ (10.65)	
Weighted-average shares used to compute basic and diluted net loss per common share	7,218,915	2,883,522	2,167,500	

See notes to consolidated financial statements

F-4

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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 Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Deferred Stock-Based Compensation	Receivable from Related Party	Notes Accumulated During the Development Stage	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount						
Balance at June 16, 1994		\$		\$	\$	\$	\$	\$	\$	\$
Issuance of common stock to subscribers for \$0.01 per share			1,785,725	18	17					
Issuance of Series A convertible preferred stock at \$0.96 per share and \$7.00 in financing costs	446,446	875			(7)					
Loss from inception to December 31, 1994									(140)	
Balance at December 31, 1994	446,446	875	1,785,725	18	10				(140)	
Loss and comprehensive loss									(327)	
Balance at December 31, 1995	446,446	875	1,785,725	18	10				(467)	
Loss and comprehensive loss									(495)	
Balance at December 31, 1996	446,446	875	1,785,725	18	10				(962)	
Loss and comprehensive loss									(787)	
Balance at December 31, 1997	446,446	875	1,785,725	18	10				(1,749)	(1,749)
Issuance of Series B convertible preferred stock at \$0.43 per share and \$4.00 in financing costs	1,358,840	4,661			(302)					

Equity-based compensation					6					
Realized holding loss on										
available-for-sale securities										
for the year ended										
December 31, 1998						(22)			(930)	
Loss										
Comprehensive loss										
Balance at December 31,										
1998	1,805,286	5,536	1,785,725	18	(286)	(22)			(2,679)	(2)
Acquisition of common										
stock issued to founders			(189,733)	(2)	(63)					
Change in fair value of common stock										
held										
at exercise of stock										
options for cash at \$0.35										
per share			613							
Change in fair value of common stock										
held at exercise of stock										
options at \$0.35 per										
share			8,948		3					
Equity-based compensation					4					
Realized holding gain on										
available-for-sale securities										
for the year ended										
December 31, 1999						3			(1,801)	(1)
Loss										
Comprehensive loss										
Balance at December 31,										
1999 (carried forward)	1,805,286	\$ 5,536	1,605,553	\$ 16	\$ (342)	\$ (19)	\$	\$	\$ (4,480)	\$ (4)

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) Continued**  
(In thousands, except share and per share data)

	Convertible		Common Stock		Additional	Accumulated	Deferred	Notes	Accumulated	Development	Share
	Preferred Stock		Shares	Amount	Paid-in	Other	Stock-Based	Receivable	During the		
	Shares	Amount	Shares	Amount	Capital	(Loss)	Compensation	Party	Stage		
December 31,											
rought forward)	1,805,286	\$ 5,536	1,605,553	\$ 16	\$ (342)	\$ (19)	\$	\$	\$ (4,480)	\$	
of Series C											
the preferred stock											
per share and											
ancing costs	1,441,539	7,487			(262)						
of Series C											
the preferred stock											
or services		12									
of Series C											
the preferred stock											
ercise of warrants											
urchase	4,813	25									
of common stock											
ercise of stock											
r cash at \$0.35 to											
share			25,827		10						
of common stock											
es at \$0.35 per			4,728		2						
ed compensation					8						
d holding gain on											
or-sale securities											
ar ended											
31, 2000							18				
									(1,363)		
nsive loss											
December 31,											
of common stock	3,251,638	13,060	1,636,108	16	(584)	(1)			(5,843)		
ercise of stock			24,554	1	8						



er cash at \$0.35 to share																			
f common stock s at \$0.52 per			6,260			3													
ed compensation d holding gain on for-sale securities						20													
ar ended 31, 2001												33							(2,554)
nsive loss																			
December 31,	3,251,638	13,060	1,666,922	17	(553)	32													(8,397)
f Series D e preferred stock er share and nancing costs	496,258	3,861				(124)													
f common stock cise of stock r cash at \$0.38 to share			216,157	2	86														
stock-based tion						9			(9)										
ion of deferred d compensation ed compensation									2										
d holding gain on for-sale securities						121													(65)
ar ended 31, 2002												16							(3,152)
nsive loss																			
December 31, ied forward)	3,747,896	\$ 16,921	1,883,079	\$ 19	\$ (461)	\$ 48	\$ (7)	\$ (65)	\$ (11,549)	\$									

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) Continued**  
**(In thousands, except share and per share data)**

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Deferred Stock-Based Compensation	Notes Receivable from Related Party	Deficit Accumulated During the Development Stage
		Shares	Amount	Shares	Amount	Capital	(Loss)	Compensation Party	Stage
December 31, right forward)	3,747,896	\$ 16,921	1,883,079	\$ 19	\$ (461)	\$ 48	\$ (7)	\$ (65)	\$ (11,549)
Series B preferred stock exercise of warrants per share	6,038	21							
of Series A preferred stock common stock exercise of stock cash at \$0.35 to share	(51,021)	(100)	178,096	2	93		4	(86)	
of deferred compensation holding loss on pre-sale securities ended December 31, 2003					406		(9)		
comprehensive loss						(37)			(4,060)
December 31, Series E preferred stock per share and financing costs common stock exercise of stock cash at \$0.35 to share	3,702,913	16,842	2,061,175	21	38	11	(12)	(151)	(15,609)
	1,873,764	18,361			(1,119)				
			28,413		10				



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		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Deferred Compensation	Notes Receivable from Related Party	Deficit Accumulated During the Development Stage
	Preferred Stock	Amount	Shares	Amount					
December 31, (right forward)	5,576,677	\$ 35,203	2,089,588	\$ 21	\$ (731)	\$ 12	\$ (79)	\$ (151)	\$ (20,187)
Series E preferred stock per share and financing costs	571,581	5,601			(278)				
common stock purchase of stock cash at \$0.35 per share			197,503	2	104				
Series C preferred stock purchase of warrants per share	16,329	84							
accrual of deferred compensation					(530)		23	(88)	
issuance of stock warrants to					(490)				
holding loss on pre-sale securities recorded									
December 31, 2005						(6)			(7,366)
comprehensive loss									
December 31, 2004	6,164,587	40,888	2,287,091	23	(1,925)	6	(56)	(239)	(27,553)
Series E preferred stock per share and	3,141,304	30,784			(1,821)				



on of deferred compensation, relations																					
l compensation of note rom related			336			6,039															
holding loss on r-sale securities ended 1, 2007																					239
sive loss																					
December 31, d forward)	11,392,057	\$	89,168	2,881,851	\$	29	\$	3,466	\$	(4)	\$	(12)	\$								
																					\$ (73,420) \$

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) Continued**  
**(In thousands, except share and per share data)**

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Deferred Stock-Based Compensation	Deficit Accumulated During the Development Stage	Shareholders' Equity
	Shares	Amount	Shares	Amount					
At December 31, 2007	11,392,057	\$ 89,168	2,881,851	\$ 29	\$ 3,466	\$ (4)	\$ (12)	\$ (73,420)	\$ 1,000,000
Exercise of stock options for cash of \$0.35 per share			69,555	1	39				
Issuance of common stock in connection with convertible preferred stock					241				
Issuance of common stock upon exercise of early-exercised convertible preferred stock options					101				
Issuance of common stock upon exercise of deferred convertible preferred stock options					2,303				
Issuance of common stock upon exercise of convertible preferred stock options and holding loss on convertible preferred stock for-sale securities							12		
At December 31, 2008						(95)		(23,827)	
Comprehensive loss									
At December 31, 2009	11,392,057	89,168	2,951,406	30	6,150	(99)		(97,247)	
Issuance of Series E convertible preferred stock of \$15.11 per share in connection with convertible preferred stock and development agreement	122,451	1,851							
Issuance of common stock upon exercise of convertible preferred stock per share upon completion of initial public offering			6,820,000	68	61,744				

6,388												
on of convertible stock to common n initial public	(11,514,508)	(91,019)	11,514,508	115	90,904							
on of preferred rant liability to on initial public						902						
of common stock rcise of stock r cash of \$0.98 to share			25,633		28							
f early-exercised ons					5							
se of rcised stock			(25,970)									
ed compensation d holding gain on for-sale securities					1,494			140	(21,089)			
ensive loss												
t December 31,	\$		21,285,577	\$	213	\$	161,227	\$	41	\$	(118,336)	\$

See notes to consolidated financial statements



Table of Contents

**OMEROS CORPORATION**  
**(A Development Stage Company)**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(In thousands)**

	Year Ended December 31,			Period from
	2009	2008	2007	June 16, 1994 (Inception) through December 31, 2009
<b>Operating activities</b>				
Net loss	\$ (21,089)	\$ (23,827)	\$ (23,091)	\$ (118,336)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	451	434	375	2,002
Stock-based compensation expense	1,494	2,315	6,056	11,652
Change in fair value of preferred stock warrant values and success fee liability	(848)	218	503	(253)
Non-cash interest expense	253	55		308
(Gain) loss on sale of investment securities	34	76	(145)	79
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	(41)	(17)	1,110	1,052
Prepaid expenses and other current and noncurrent assets	42	19	(22)	(130)
Deferred public offering costs		(486)	(1,462)	(1,948)
Accounts payable and accrued expenses	207	(140)	3,162	4,865
Deferred revenue	470	(268)	(800)	(598)
Net cash used in operating activities	(19,027)	(19,673)	(14,314)	(88,305)
<b>Investing activities</b>				
Purchases of property and equipment	(279)	(164)	(534)	(2,072)
Purchases of investments	(64,207)		(30,562)	(148,104)
Proceeds from the sale of investments	11,045	5,572	11,450	43,716
Proceeds from the maturities of investments	1,039	5,158	13,555	44,703
Cash paid for acquisition of nura, net of cash acquired of \$87				(212)
Net cash (used in) provided by investing activities	(52,402)	10,566	(6,091)	(61,969)

**Financing activities**

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		16,878		16,928
Payments on notes payable	(4,120)	(1,010)	(1,005)	(6,576)
Proceeds from issuance of common stock upon exercise of stock options	28	40	360	670
Proceeds from the repayment of related party notes receivable			239	239
Proceeds from issuance of convertible preferred stock, net of issuance costs	1,851		3,336	78,234
Repurchase of unvested common stock and Series A convertible preferred stock	(48)			(213)
Net cash provided by financing activities	59,523	15,908	2,930	151,094
Net (decrease) increase in cash and cash equivalents	(11,906)	6,801	(17,475)	820
Cash and cash equivalents at beginning of period	12,726	5,925	23,400	
Cash and cash equivalents at end of period	\$ 820	\$ 12,726	\$ 5,925	\$ 820

**Supplemental cash flow information**

Cash paid for interest	\$ 1,947	\$ 222	\$ 151	\$ 2,463
Purchase of equipment included in accounts payable and accrued expenses	\$ 280	\$ 52	\$	\$ 332
Purchase of software financed with note payable	\$	\$ 193	\$	\$ 193
Vesting of early-exercised stock options	\$ 5	\$ 101	\$	\$ 106
Issuance of warrants in connection with notes payable	\$	\$ 241	\$	\$ 241
Issuance of common stock in exchange for note receivable from related party	\$	\$	\$	\$ 239
Preferred stock and common stock issued in connection with nura acquisition	\$	\$	\$	\$ 14,070

See notes to consolidated financial statements

**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1 Organization and Significant Accounting Policies**

*Organization*

Omeros Corporation (Omeros or the Company) is a biopharmaceutical company committed to discovering, developing and commercializing products focused on inflammation and disorders of the central nervous system. The Company's most clinically advanced product candidates are derived from its proprietary PharmacoSurgery<sup>™</sup> platform designed to improve clinical outcomes of patients undergoing arthroscopic, ophthalmological, urological and other surgical and medical procedures. As substantially all efforts of the Company have been devoted to conducting research and development of its products, to developing its patent portfolio and to raising equity capital, the Company is considered to be in the development stage.

*Basis of Presentation*

The consolidated financial statements include the financial position and results of operations of Omeros and nura, inc. (nura), its wholly-owned subsidiary. The acquisition of nura was accounted for as an asset purchase, and the results of nura have been included in the results of the Company since August 11, 2006.

*Reverse Stock Split*

On August 13, 2009 and September 8, 2009, the Board of Directors and shareholders, respectively, approved a 1-for-1.96 reverse stock split of the Company's convertible preferred stock and common stock. The Company effected the reverse stock split on October 2, 2009. All share and per share amounts have been retroactively restated in the accompanying financial statements and notes for all periods presented.

*Initial Public Offering*

On October 7, 2009, the Company's Registration Statement on Form S-1/A was declared effective. The Company sold 6,820,000 shares of its common stock at a price of \$10.00 per share. The Company received gross proceeds of \$68.2 million from this transaction, before underwriting discounts and commissions. In connection with the closing of the Company's initial public offering (IPO), all of the Company's shares of preferred stock outstanding at the time of the offering were automatically converted into 11,514,508 shares of common stock, and Series E preferred stock warrants to purchase up to 197,478 shares of Series E convertible preferred stock were converted into common stock warrants to purchase 197,478 shares. Upon the completion of the IPO on October 13, 2009, the authorized capital stock of the Company consisted of 150,000,000 shares of common stock and 20,000,000 shares of preferred stock, each with a par value of \$0.01 per share.

*Financial Instruments and Concentrations of Credit Risk*

The fair values of 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 the Company 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, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its 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.

**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*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. 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. The Company evaluates 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 the Company's 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 the Company's IPO activities 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 term of the lease or five years, whichever is shorter.

*Intangible Assets*

In August 2006, the Company acquired certain intangible assets related to the acquisition of nura. The Company assigned a value of \$310,000 to assembled and trained workforce with an amortizable life of three years. The accumulated amortization of the assembled workforce was \$310,000 and \$250,000 at December 31, 2009 and 2008, respectively. The intangible assets were fully amortized as of December 31, 2009.

*Impairment of Long-Lived Assets*

The carrying amount of long-lived assets, including property and equipment and intangible assets, that are not considered to have an indefinite useful life, 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

F-12

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**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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. No impairment has been recognized by the Company.

*Deferred Rent*

The Company recognizes rent expense on a straight-line basis over the noncancelable term of its operating leases and, accordingly, records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. The Company also records 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 its operating leases.

*Preferred Stock Warrant Liability*

Prior to the completion of the IPO, warrants to purchase the Company's 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, 2008 and 2007, the Company recorded income (expense) of \$878,000, \$(218,000) and \$(503,000), 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 the Company's IPO in October 2009 with the conversion of all of the preferred stock warrants to common stock warrants.

*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.

The Company's revenue since inception relates to grant funding from third parties. The Company recognizes 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 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 the Company's clinical programs; contracted research; manufacturing; related consulting arrangements; and other expenses incurred to sustain the Company's overall research and development programs. Internal research and development costs are expensed 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. Clinical trial expenses require certain estimates based upon an estimated cost per patient that varies depending on the clinical site and trial.

*In-Process Research and Development*

In connection with the acquisition of nura in August 2006, the Company recorded an expense of \$10.9 million for acquired in-process research and development. This amount represented the estimated fair

F-13

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**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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*

The Company generally applies 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.

*Other Comprehensive Loss*

Other comprehensive loss is comprised of net loss and certain changes in equity that are excluded from net loss. The Company's only component of other comprehensive loss is unrealized gains (losses) on available-for-sale securities. The components of other comprehensive loss are as follows:

	<b>Year Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
	<b>(in thousands)</b>		
Net loss	\$ (21,089)	\$ (23,827)	\$ (23,091)
Unrealized gain (loss) on available-for-sale securities	140	(95)	(30)
Other comprehensive loss	\$ (20,949)	\$ (23,922)	\$ (23,121)

*Stock-Based Compensation*

The Company accounts for stock-based compensation under applicable accounting standards using the prospective method, which requires that the measurement and recognition of compensation expenses for all future share-based payments made to employees and directors be based on estimated fair values. The Company is 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.

For purposes of estimating the fair value of its common stock for stock options granted prior to the IPO, the Company estimated fair value of its common stock by performing a valuation analysis for each quarterly period during the six months ended June 30, 2009 and the years ended December 31, 2008 and 2007. For the quarter ended September 30, 2009, the Company used the \$10.00 per share offering price from its IPO, which was declared effective by the SEC on October 7, 2009 and completed on October 13, 2009. As a result, certain stock options granted during 2009 and 2008 and all options granted in 2007 had an exercise price different than the re-assessed estimated fair value of the common stock at the date of grant. The Company used these fair value estimates derived from its valuations to determine the stock compensation expense, which is recorded in its consolidated financial statements. The valuations were prepared using a methodology that first estimated the fair value of the company as a whole, and then allocated a portion of the enterprise

**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

value to common stock. Subsequent to the IPO, the Company uses the closing market price of the Company's common stock on the date of grant.

*Segments*

The Company operates in only one segment. Management uses cash flow as the primary measure to manage its business and does not segment its business for internal reporting or decision-making.

*Adoption of Standards*

*Accounting Standards Codification.* In June 2009, the Financial Accounting Standards Board (FASB) approved the Accounting Standards Codification which became the single source of authoritative United States accounting and reporting standards other than guidance issued by the Securities and Exchange Commission. The Accounting Standards Codification is a major restructuring of accounting and reporting standards; however, the codification is not intended to change existing standards. The Accounting Standards Codification was effective for interim and annual periods ending after September 15, 2009.

*Collaborative Arrangements.* Effective January 1, 2009, the Emerging Issues Task Force (EITF) issued guidance over accounting for collaborative arrangements. This guidance requires disclosure of the nature and purpose of the Company's significant collaborative arrangements in the annual financial statements, including the Company's rights and obligations under the arrangement, the amount and income statement classification of significant financial expenditures and commitments, and a description of accounting policies for the arrangement. This guidance requires the Company to apply as a change in accounting principle through retrospective application to all prior periods for all applicable collaborative arrangement existing as of the effective date. There was no impact to the Company's results of operations or financial position upon adoption.

*Fair Value Measurements.* In April 2009, the FASB issued authoritative guidance for interim disclosures about fair value of financial instruments, which amended existing guidance. This guidance is effective for interim and annual periods ending after June 15, 2009 and expands guidance on (a) measuring the fair value of financial instruments when market activity has decreased and quoted prices may reflect distressed transactions, (b) the recognition and presentation of other-than-temporary impairments on debt and equity securities and (c) the fair value disclosures required for financial instruments in interim reporting periods. The adoption of the fair value guidance did not impact the Company's financial condition or results of operations.

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.

**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.

Table of Contents

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Net loss attributable to common shareholders for each period must be allocated to common stock and participating securities to the extent that the securities are required to share in the losses. As a result, basic net loss per common share is calculated by dividing net loss by the weighted-average shares of common stock outstanding during the period.

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

	<b>Year Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Historical</b>			
<b>Numerator:</b>			
Net loss	\$ (21,089)	\$ (23,827)	\$ (23,091)
<b>Denominator:</b>			
Weighted-average common shares outstanding	7,233,109	2,937,789	2,684,162
Less: Weighted-average unvested common shares subject to repurchase	(14,194)	(54,267)	(43,228)
Less: Common shares subject to shareholder note receivable			(473,434)
Denominator for basic and diluted net loss per common share	7,218,915	2,883,522	2,167,500
Basic and diluted net loss per common share	\$ (2.92)	\$ (8.26)	\$ (10.65)

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

	<b>December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Convertible preferred stock		11,392,057	11,392,057
Outstanding options to purchase common stock	2,847,549	2,839,851	3,014,309
Common stock subject to shareholder note receivable			473,434
Warrants to purchase common stock and convertible preferred stock	209,017	234,230	209,017
Common stock subject to repurchase		28,762	80,882
Total	3,056,566	14,494,900	15,169,699



Table of Contents

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**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:

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

	<b>December 31, 2008</b>			
	<b>Amortized</b>	<b>Gross</b>	<b>Gross</b>	<b>Fair Value</b>
	<b>Cost</b>	<b>Unrealized</b>	<b>Unrealized</b>	
		<b>Gains</b>	<b>Losses</b>	
		<b>(in thousands)</b>		
Cash and cash equivalents	\$ 12,919	\$	\$	\$ 12,919
Mortgage-backed securities	7,355	3	(102)	7,256
<b>Total</b>	<b>\$ 20,274</b>	<b>\$ 3</b>	<b>\$ (102)</b>	<b>\$ 20,175</b>
Amounts classified as cash and cash equivalents				\$ 12,726
Amounts classified as restricted cash				193
Amounts classified as short-term investments				7,256
<b>Total</b>				<b>\$ 20,175</b>

The following table shows the fair value of the Company's investments securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and by whether the securities have been in a continuous unrealized loss position for less than 12 months or for 12 months or greater as of December 31, 2009 and 2008, respectively.

Description of Securities	Less than 12 Months		December 31, 2009 12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value (in thousands)	Unrealized Losses	Fair Value	Unrealized Losses
Mortgage-backed securities	\$ 116	\$	\$ 26	\$	\$ 142	\$

F-17



Table of Contents

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Description of Securities	Less than 12 Months		December 31, 2008		Total	
	Unrealized		12 Months or Greater		Unrealized	
	Fair Value	Losses	Fair Value	Losses	Fair Value	Losses
	(in thousands)					
Mortgage-backed securities	\$ 4,512	\$ (59)	\$ 2,123	\$ (43)	\$ 6,635	\$ (102)

The Company owned two and nine securities with unrealized loss positions as of December 31, 2009 and 2008, respectively. The two securities with the unrealized loss positions as of December 31, 2009 were immaterial. The Company believes the unrealized losses in the table above are not other-than-temporary. The unrealized losses are driven primarily by market conditions that have caused price deterioration. The Company assesses the fundamentals of these securities to identify their individual sources of risk and potential for other-than-temporary impairment. The assessment includes a review of performance indicators of the underlying assets in the security, loan to collateral value ratios, third-party guarantees, vintage, geographic concentration, industry analyst reports, sector credit ratings, volatility of the security's fair value, current market liquidity, reset indices, prepayment levels, credit rating downgrades 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.

The Company's investment portfolio is made up of cash, cash equivalents, and mortgage-backed, adjustable-rate securities issued by, or fully collateralized by, the U.S. government or U.S. government-sponsored entities. The mortgage-backed securities have contractual maturities ranging from six to 28 years at December 31, 2009, and ranging from seven to 31 years at December 31, 2008. Due to normal annual prepayments, the estimated average life of the portfolio is approximately three to five years. The adjustable rate feature, which is not dependent on an auction process, further shortens the duration and interest risk of the portfolio, making it similar to a one-year government agency security. All investments are classified as short-term and available-for-sale on the accompanying balance sheets.

To determine the fair market value of its mortgage-backed securities, the Company's 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 the Company's portfolio. The Company has used this non-binding pricing information to estimate fair market value and does 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 the Company's investment income is as follows:

	Year Ended December 31,		
	2009	2008	2007
	(in thousands)		
Gross interest income	\$ 249	\$ 737	\$ 1,437
Gross realized gains on investments	7	16	310
Gross realized losses on investments	(42)	(92)	(165)
Total investment income	\$ 214	\$ 661	\$ 1,582

F-18

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Table of Contents

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Realized gains and losses on sales of investments are calculated based on the specific identification method.

**Note 4 Fair Value Measurements**

The accounting standard for fair value measurements provides a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. Under this standard, 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.

As of December 31, 2009 and 2008, no assets or liabilities are measured at fair value on a nonrecurring basis. As of December 31, 2009, no financial liabilities remain. The Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis are as follows:

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

	Level 1	December 31, 2008		Total
		Level 2	Level 3	
(in thousands)				
Assets:				
Money market funds	\$ 12,783	\$	\$	\$ 12,783
Mortgage-backed securities		7,256		7,256
Total	\$ 12,783	\$ 7,256	\$	\$ 20,039

Liabilities:

Preferred stock warrant liability	\$	\$	\$ 1,780	\$ 1,780
Notes payable success fee liability			310	310
Total	\$	\$	\$ 2,090	\$ 2,090

The change in fair value of the Company's short-term investments are included in accumulated other comprehensive income (loss) in the accompanying balance sheets. The change in fair value of the Company's preferred stock warrant liability and notes payable success fee liability are recorded as other income (expense) in the consolidated statements of operations. For the years ended December 31, 2009 and 2008, respectively,

Table of Contents

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

the change in fair value of the preferred stock warrant liability and notes payable success fee liability are as follows:

	<b>Preferred Stock Warrant Liability (in thousands)</b>	<b>Notes Payable Success Fee Liability (in thousands)</b>
Fair value at December 31, 2008	\$ 1,780	\$ 310
Change in fair value included in earnings	(878)	30
Settlements		\$ (340)
Transfers out	(902)	
Fair value at December 31, 2009	\$	\$

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. See Note 6 for a discussion of the valuation methodology used to estimate the fair value of the notes payable success fee liability and the payment of the success fee following completion of the IPO.

**Note 5 Certain Balance Sheet Accounts***Grant and Other Receivables*

Grant and other receivables consisted of the following:

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in thousands)</b>	
Grant revenue receivable	\$ 143	\$ 180
Other receivables	105	27
Grant and other receivables	\$ 248	\$ 207

*Property and Equipment*

Property and equipment consisted of the following:

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in thousands)</b>	
Computer equipment	\$ 279	\$ 266
Computer software	379	319
Office equipment and furniture	284	284
Leasehold improvements	278	278
Laboratory equipment	1,503	1,016
Total	2,723	2,163
Less accumulated depreciation and amortization	(1,637)	(1,245)
Property and equipment, net	\$ 1,086	\$ 918

The Company's 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, 2009, 2008 and 2007 was \$392,000, \$330,000 and \$272,000 respectively.

**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Accrued Expenses*

Accrued expenses consisted of the following:

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in thousands)</b>	
Clinical trials	\$ 1,868	\$ 1,644
Employee compensation	324	319
Contract preclinical research	60	423
Success fee liability related to notes payable		310
Public offering costs		345
Other accruals	585	723
Accrued expenses	\$ 2,837	\$ 3,764

See Note 6 for a discussion of the success fee liability.

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

In September 2008, the Company entered into a loan and security agreement with BlueCrest Capital Finance, L.P. (BlueCrest) to borrow up to \$20.0 million in four tranches. The Company has borrowed a total of \$17.0 million under the agreement. Interest on borrowings under the loan agreement is at an annual rate of 12.5%. Repayments of advances under the loan are made monthly, on the first of the month following the date of each applicable advance. Payments were interest only for the first three months and interest and principal thereafter for 36 months. Under the loan agreement, the Company must comply with affirmative and negative covenants and, if any event, condition, or change occurs that has a material adverse effect (as defined in the agreement), BlueCrest may require immediate repayment of all borrowings then currently outstanding.

Material adverse effect (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 the Company, taken as a whole with respect to the Company's viability, that reasonably would be expected to result in the Company's 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 BlueCrest'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 BlueCrest to enforce its rights and remedies under the loan agreement or related agreements. The Company considered the MAE definition in the agreement as subjective and classified all of the outstanding notes payable as current liabilities in the consolidated balance sheet as of December 31, 2008 based on the uncertainty as to whether BlueCrest would utilize the material adverse effect clause and call a portion or all of the notes payable to them. However, due to the improved liquidity following the completion of the Company's IPO, the

Company believes that it is less likely that the MAE clause would be triggered, and accordingly, the portion of the note payable that is due in more than one year has been classified as a long-term liability as of December 31, 2009.

The proceeds of the loan may be used for working capital, capital expenditures and general corporate purposes, and the loan is collateralized by substantially all of the Company's assets, other than intellectual property. The Company may prepay the outstanding principal amount of all loans then outstanding in whole, but not in part, by providing 30 days written notice. However, a prepayment premium of 2.0% applies if the prepayment is made within 18 months after the borrowing date of the applicable draw. If a prepayment is made more than 18 months after the date of the applicable draw, then the prepayment premium is reduced to 1.0%.



**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As a condition to BlueCrest making the initial \$5.0 million loan, the Company agreed to pay a fee (Success Fee) to BlueCrest in an amount up to \$400,000 should certain exit events (as defined) occur prior to September 12, 2018. The Success Fee was pro rated based on the ratio of the actual amounts borrowed under the loan agreement to the total \$20.0 million that could be borrowed. An exit event is defined in the agreement as including, among other things, a change in control of the Company, a sale of all or substantially all of the Company's assets, or an initial public offering of the Company's common stock. The Success Fee was determined to be an embedded derivative which was recorded at estimated fair value in the accompanying financial statements. Based on the \$17.0 million borrowed under the loan agreement the Success Fee was estimated to be \$310,000 at December 31, 2008 and following the completion of the IPO, \$340,000 was paid to BlueCrest. The fair value of the pro rated Success Fee was estimated at the time of borrowing based on the estimated probability and date of occurrence of the exit events, discounted to present value using the Company's estimated cost of capital. The fair value of the fee was recorded as a success fee liability with an offsetting reduction in notes payable accounted for as a debt discount. The debt discount is being amortized to interest expense using the effective interest method over the repayment term of the initial loan amount. The success fee liability was adjusted to fair value on a recurring basis, with changes in fair value recorded as other income (expense) in the consolidated statements of operations. The Company has no further obligation to pay a success fee to BlueCrest.

In connection with the execution of and subsequent draws under the loan and security agreement, the Company issued two warrants to BlueCrest to purchase common stock at an exercise price of \$13.48 per share. The warrants vested in tranches as amounts were borrowed under the loan agreement. These warrants terminated, without being exercised, on October 13, 2009 upon completion of the Company's IPO. As of December 31, 2009 and 2008, a total of 0 and 25,213, respectively, common stock warrants had vested and were outstanding under the first warrant in connection with the drawdowns of the first three tranches available under the loan agreement. The fair value of the vested warrant was \$241,000, determined using the Black-Scholes option-pricing model, and was recorded as additional paid-in capital and as a discount to the note. The debt discount 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 \$204,000 and \$41,000 for the years ended December 31, 2009 and 2008, respectively. The first warrant was fully vested as of December 31, 2009 and, because the Company did not borrow the fourth tranche, no shares will vest under the second warrant. The fair value of the second warrant was determined to be \$0 based on the probability that the funds available for borrowing under the fourth tranche of the loan agreement would not be drawn.

In connection with the loan and security agreement, the Company incurred debt issuance costs of \$122,000 that were capitalized and included in other assets in the December 31, 2008 balance sheet. The debt issuance costs are 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 issuance costs totaled \$49,000 and \$14,000 for the years ended December 31, 2009 and 2008, respectively. The remaining unamortized balance is \$59,000 at December 31, 2009 and is included in other assets in the balance sheet.

*Software Financing Arrangement*

In December 2008, the Company 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%.



**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Future Principal Payments*

Future principal payments as of December 31, 2009 under the loan and security agreement and the software financing arrangement based on stated contractual maturities are as follows (in thousands):

<b>Year Ending December 31,</b>	<b>Loan and Security Agreement</b>	<b>Software Financing Arrangement</b>	<b>Total</b>
2010	5,029	78	5,107
2011	6,182	54	6,236
2012	1,730		1,730
Total principal payments	12,941	132	13,073
Less current portion	(5,029)	(78)	(5,107)
Total notes payable, net of current portion	\$ 7,912	\$ 54	\$ 7,966

The unamortized debt discount is \$315,000 and \$519,000 at December 31, 2009 and 2008, respectively.

**Note 7 Revenue**

The Company has received Small Business Innovative Research (SBIR) grants from the National Institutes of Health since inception totaling \$3.2 million and \$2.3 million as of December 31, 2009 and 2008, respectively. The purpose of the grants is to support research for product candidates being developed by the Company. For the years ended December 31, 2009, 2008 and 2007, the Company recorded revenue related to these grants of \$432,000, \$670,000 and \$1.1 million, respectively. As of December 31, 2009, \$687,000 remained under these grants.

In December 2006, the Company entered into a funding agreement with The Stanley Medical Research Institute (SMRI) to develop a proprietary PDE10 inhibitor product candidate for the treatment of schizophrenia. The funding is expected to advance the Company's PDE10 program through the completion of Phase 1 clinical trials. Under the agreement, the Company may receive grant and equity funding of up to \$9.0 million upon achievement of research milestones. The Company holds the exclusive rights to the technology. In consideration for SMRI's grant funding, the Company 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, the Company is not required to repay the grant funds. As of December 31, 2009 and 2008, the Company has received from SMRI a total of \$5.7 million and \$2.6 million, respectively. As of December 31, 2009, amounts included in the accompanying balance sheet pertaining to this agreement included \$702,000 in deferred revenue. In addition, in 2007 and 2009 the Company 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, 2009, 2008 and 2007, the Company recognized revenue under this agreement of \$548,000, \$500,000 and \$800,000, respectively.

In November 2008, the Company entered into an agreement with The Michael J. Fox Foundation (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. The Company holds and will continue to hold the exclusive rights to the technology and has no future obligation to MJFF for royalties or other monetary consideration resulting from the ongoing development of the technology. The Company has 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. For the year ended

F-23

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**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

December 31, 2009 all \$464,000 of funds have been recognized as revenue as the related expenses were incurred. No revenue was recognized under this agreement prior to 2009.

**Note 8 Acquisition of nura**

Effective August 11, 2006, the Company acquired nura, inc. (nura), a private biotechnology company which expanded and diversified the Company's potential product pipeline and strengthened its discovery capabilities. The Company completed the acquisition of nura through the issuance of 1,733,914 shares of Omeros Series E convertible preferred stock and 18,498 shares of common stock, and the assumption of a \$2.4 million promissory note. 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 Company recorded the convertible preferred stock issued to the nura stockholders at its fair value of \$14.4 million. In valuing the nura acquisition, the Company followed guidance covering business combinations, which states the value is measured on the fair value of the consideration given or the fair value of the asset acquired, whichever is more clearly evident and, thus, more reliably measurable. Because the tangible assets of nura were minor in comparison to the intangible assets acquired, the Company believed that the fair value of the consideration given, the Company's preferred stock issued, was more clearly evident and measurable.

The value of \$14.4 million was based upon the implied value of the Company's preferred stock considering the enterprise value of the Company at the date of the transaction, as well as considering the value of the assets received. The valuation methodology relied primarily on the income approach. The Company's enterprise value was then allocated to the different classes of equity using the option pricing method, with a resulting Series E preferred stock implied value of \$4.14 per share. In allocating the enterprise value to the various classes of equity, the Company made the following assumptions: 0.75 year period to liquidity; 49.0% volatility metric; 0.0% dividend yield; and a risk-free interest rate of 5.05%. Since the Company's preferred stock was not publicly traded in 2006, the Company estimated the fair value of the assets (consideration) received in the transaction, consisting primarily of acquired in-process research and development as described in more detail below. The results of this analysis of the assets acquired corroborated the value of the \$14.4 million recorded in the transaction.

The aggregate purchase price of nura was \$14.4 million, consisting of the issuance of 1,733,914 shares of Omeros convertible preferred stock, 18,498 shares of Omeros common stock and \$299,000 in direct transaction costs. The purchase price was allocated as follows (in thousands):

Cash	\$	87
Prepaid assets and other current assets		233
Cash investment from existing nura institutional investors		5,200
Equipment		182
Assumed liabilities		(2,535)

Net tangible assets	3,167
Assembled workforce	310
Acquired in-process research and development	10,891
Total fair value of assets acquired, net of liabilities assumed	\$ 14,368

F-24

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**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Assumed liabilities include notes payable of \$2.4 million, accounts payable and accrued expenses of \$65,000, and preferred stock warrant liability of \$64,000.

The value assigned to the assembled workforce was being amortized over three years. The value assigned to acquired in-process research and development represented the fair value of nura's incomplete research and development programs that had not yet reached technological feasibility and had no alternative future use as of the acquisition date.

nura's research and development activities were very early stage and none of its product candidates had yet entered clinical studies. Based on a review of the acquired research and development technology, management believed that the economic benefit associated with the acquisition of nura related to only one of the preclinical product candidates, PDE10. PDE10 product candidates were at the time being developed by other life science companies, indicating potential to commercialize the acquired technology.

The acquired in-process research and development was valued at \$10.9 million and was recorded as an operating expense in 2006. The value was determined using the income approach whereby estimated future net cash flows of the PDE10 program from 2007 to 2026 were discounted to present value using a risk-adjusted discount rate of 40%.

As a preclinical product candidate, the ability of the Company to successfully commercialize PDE10 is highly uncertain. It is expected to take a number of years to conduct the necessary preclinical and clinical studies to file for product approval with the FDA and there is no assurance that such studies will be successful. The Company's development effort for PDE10 is currently supported by funds from SMRI, a nonprofit corporation that supports research on the causes and treatment of schizophrenia and bipolar disorder.

**Note 9 Commitments and Contingencies**

The Company leases laboratory and corporate office space, and rents equipment under operating lease agreements which include certain rent escalation terms. The laboratory space lease term extends through September 30, 2011 and the lease term for the corporate office space expires August 31, 2011. Rental of equipment extends into 2013. The Company subleases a portion of its leased properties. Future minimum payments related to the leases, which exclude common area maintenance and related operating expenses, at December 31, 2009, are as follows:

<b>Year Ending December 31,</b>	<b>Lease Payments</b>	<b>Sublease Income (in thousands)</b>	<b>Net Lease Payments</b>
2010	1,563	554	1,009
2011	1,134	1	1,133
2012	23		23
2013	15		15
Total	\$ 2,735	\$ 555	\$ 3,452

Rent expense totaled \$2.3 million, \$2.0 million and \$1.9 million for the years ended December 31, 2009, 2008 and 2007, respectively. Rental income received under noncancelable subleases was \$799,000, \$587,000 and \$378,000 for the years ended December 31, 2009, 2008 and 2007, 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, the Company 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, 2009, the



**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

maximum amount of royalties payable by the Company is \$12.8 million. The Company has not paid any such royalties through December 31, 2009.

In July 2008, the Company entered into a discovery and development agreement with Affitech AS (Affitech) to isolate and optimize fully human antibodies for the Company's mannan-associated serine protease-2 (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 the Company. The Company recorded research and development expense under the agreement totaling \$0 and \$400,000 in 2009 and 2008, respectively. In March 2010, the Company and Affitech amended their antibody development agreement. Under the terms of the amendment, Affitech released the Company 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 the Company for a fee. The agreement may be terminated for cause by either party, or at any time by the Company by providing 30 day advance written notice to Affitech.

In September 2008, the Company entered into a technology option agreement with Patobios Limited (Patobios) to evaluate and potentially acquire the intellectual property rights covering Patobios' G protein-coupled receptor (GPCR) technology. Under the terms of the agreement, as amended in November 2009, Patobios granted the Company an option to evaluate the technology over four option periods commencing September 2008 and continuing up to December 2010. The Company 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 the Company of \$108,000 CAD (\$104,000 USD) and Omeros had exercised its right to extend the third option period from January 2010 to June 2010 at a cost to the Company of \$542,000 CAD (\$516,000 USD), which was recorded as expense in 2009. The Company may also extend the option period for one additional six-month period ending December 2010 at a cost of \$500,000 CAD. Under the terms of the agreement, the Company has the exclusive option to acquire the intellectual property rights, including patents, covering Patobios' GPCR technology at any time during any of the option periods for a total acquisition price of \$10.8 million CAD in cash and stock. In addition, if the Company achieves the de-orphanization milestone, it will be required to pay Patobios a \$500,000 CAD milestone payment that would be credited against the cash portion of the \$10.8 million CAD purchase price. Also, following achievement of the de-orphanization milestone, the Company will be required to purchase the GPCR technology from Patobios for the \$10.8 million CAD purchase price if, during the term of the agreement, the sum of the following items is at least equal to \$5.1 million CAD: (a) the amount paid by the Company to Patobios from licenses granted by the Company to third parties for the development and commercialization of the de-orphanized GPCRs, (b) the amount of any government or non-profit funding received by the Company specifically allocated for the purchase of the GPCR technology and (c) the \$500,000 CAD de-orphanization milestone payment. The agreement may be terminated for cause by either party, at any time by mutual consent of the Company and Patobios, or by the Company at any time prior to the achievement of the de-orphanization milestone.

In October 2008, the Company entered into an antibody development agreement with North Coast Biologics LLC (North Coast) to isolate and optimize antibodies for the Company's 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 the Company. The Company recorded research and development expenses under the agreement totaling \$0 and \$150,000 for the years ended December 31, 2009 and 2008, respectively. Under the agreement, the Company

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

F-26

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**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

North Coast. The agreement also provides an option to the Company to have North Coast generate antibodies for additional targets. If this option is exercised, the Company 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, the Company is obligated to pay North Coast a low single-digit percentage royalty on any net sales by the Company 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, the Company entered into a patent assignment agreement with an individual whereby the Company acquired all intellectual property rights, including patent applications, related to peroxisome proliferators activated receptor 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. Under the agreement, the Company may be required to make payments of up to \$2.3 million to the individual upon achievement of certain development events, such as the initiation of clinical trials and receipt of marketing approval. In addition, the Company is 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, the Company entered into a license agreement with Asubio Pharma Co., Ltd. (Asubio) pursuant to which the Company received an exclusive license to PDE7 inhibitors claimed in certain patents and pending patent applications owned by Asubio for use in the treatment of movement disorders and other specified indications. Under the agreement, the Company agreed to make milestone payments to Asubio 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, Asubio is entitled to receive from the Company a low single-digit percentage royalty of any net sales of a PDE7 inhibitor licensed under the agreement by the Company and/or its sublicensee(s), provided that if the sales are made by a sublicensee, then the amount payable by the Company to Asubio is capped at an amount equal to a low double-digit percentage of all royalty and specified milestone payments received by the Company from the sublicensee.

**Note 10 Warrants**

On August 24, 2009, in connection with the IPO, the Company 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 the Company's Series E convertible preferred stock financing. The holders of these warrants include 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. The Company 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 (expense), was included in other income (expense). 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.



**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following is a table summarizing the warrants outstanding as of:

	December 31, 2009			December 31, 2008		
	Warrants Outstanding	Fair Value	Weighted- Average Exercise Price	Warrants Outstanding	Fair Value	Weighted- Average Exercise Price
Common stock	209,017	\$	\$ 12.08	25,246	\$	\$ 13.47
Series E preferred stock				208,983	1,780	12.08
Total	209,017	\$	\$ 12.08	234,229	\$ 1,780	\$ 12.23

The common stock warrants are recorded in permanent equity and are not adjusted to fair value on a recurring basis. Until the completion of the Company's IPO the fair value of the preferred stock warrants is classified as a liability on the Consolidated Balance Sheet and was adjusted to fair value at the end of each reporting period. Such fair values were estimated using the Black-Scholes option pricing model, based on the following assumptions:

	December 31, 2008
Risk-free interest rate	2.3%
Weighted-average expected life (in years)	3.25-5.00
Expected dividend yield	
Expected volatility rate	71%

The increase (decrease) in the fair value of the warrants totaled \$(878,000), \$218,000 and \$503,000 during the years ended December 31, 2009 and 2008, respectively. These changes in the preferred stock warrant liability are included in other income (expense) in the consolidated statement of operations.

No revaluation was necessary at December 31, 2009 as the remaining preferred stock warrant liability of \$902,000 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.

**Note 11 Shareholders Equity***Preferred Stock*

In connection with the closing of the IPO, all of the Company's shares of preferred stock outstanding at the time of the offering were automatically converted into 11,514,508 shares of common stock. As of December 31, 2009 no liquidation preference remained. Liquidation preference as of December 31, 2008 was \$92.1 million. Upon the

completion of the Company's initial public offering, the authorized preferred stock consists of 20,000,000 shares of preferred stock, with a par value of \$0.01 per share.

The Company's Second Amended and Restated Articles of Incorporation authorized the Company to issue shares of Series A through Series E convertible preferred stock, which hereafter are collectively referred to as convertible preferred stock.

On February 27, 2007, the Company issued 339,807 shares of Series E convertible preferred stock at \$9.80 per share, raising net proceeds of \$3.2 million. The Company also committed to issue warrants to purchase 4,490 shares of Series E convertible preferred stock at \$12.25 per share upon the final close of the Series E financing.

On February 18, 2009, the Company received \$3.1 million in connection with the funding agreement with SMRI. Under the terms of the agreement with SMRI, entered into in December 2006, \$1.9 million of the funding is characterized as grant funding and the remaining \$1.2 million is characterized as equity funding for the purchase of 122,449 shares of the Company's Series E convertible preferred stock at a price of \$9.80 per share. At the time of issuance of the Series E convertible preferred stock to SMRI in February 2009, the

**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

estimated fair value of the 122,449 shares was \$1.9 million, or \$15.11 per share, rather than the \$1.2 million characterized as equity funding under the agreement. Accordingly, the Company recorded \$1.9 million to equity for the 122,449 shares issued to SMRI and the remaining \$1.2 million of the proceeds from SMRI as deferred revenue.

As discussed in Note 8, effective August 11, 2006, the Company 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 invested in the Company through the purchase of 530,614 shares of Series E convertible preferred stock for \$5.2 million.

*Common Stock*

The Company has reserved shares of common stock for the following purposes as of:

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
Options granted and outstanding under the 2008 stock option plan	201,129	25,611
Options available for future grant under the 2008 stock option plan	1,013,256	1,020,728
Options granted and outstanding under the 1998 stock option plan	2,613,438	2,781,152
Options granted and outstanding outside of the stock option plans	30,001	30,001
Options granted and outstanding under the nura 2003 stock option plan	2,981	3,086
Conversion of convertible preferred stock		11,392,057
Convertible preferred stock warrants		208,983
Common stock warrants	209,017	25,247
<b>Total shares reserved</b>	<b>4,069,822</b>	<b>15,486,865</b>

*Stock Repurchases*

Prior to 2004, the Company repurchased 189,733 shares of common stock for \$65,000. Upon purchase, these shares were canceled. Shares were repurchased in an amount equal to the exercise price of the shares. During 2004, the Company repurchased 51,021 shares of convertible preferred stock upon resolution of a legal matter that existed prior to 2004. The Company recorded the repurchased shares as a deduction of \$100,000 from convertible preferred stock at December 31, 2003, which was equal to the original purchase price of the shares.

The Company accounts for cash received in consideration for the purchase of unvested shares of common stock or the early-exercise of unvested stock options as a current liability, which is included as a component of accrued liabilities on the Company's balance sheet. As of December 31, 2009 and 2008 there were 0 and 28,762 unvested shares of the Company's common stock outstanding, respectively, and \$0 and \$54,000 of related recorded liability, respectively, which was included in accrued liabilities.

In February 2009, the Company repurchased 2,584 shares of unvested stock for their original exercise price of \$0.98 per share. In August 2009, the Company repurchased an additional 23,384 shares of unvested stock for their original exercise price of \$1.96 per share. All of these unvested shares had been issued in connection with the early exercise of stock options. In accordance with the provisions of the 2008 Plan, the repurchased shares increased the authorized shares available under the 2008 Plan.



**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 12 Stock-Based Compensation**

*Stock Options*

In February 2008, the Company's board of directors adopted the 2008 Equity Incentive Plan (the 2008 Plan) which was subsequently approved by the Company's shareholders in March 2008. 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 the Company's Amended and Restated 1998 Stock Option Plan (the 1998 Plan), as a result of cancellation of options or repurchase of shares issued pursuant to the 1998 Plan, to be issued under the 2008 Plan subject to a maximum limit of 3,084,848 shares. As of and December 31, 2009 and 2008, an additional 321,528 and 153,479 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 the Company's common stock on the last day of the immediately preceding fiscal year;

1,785,714 shares; or

such other amount as the Company's board of directors may determine.

On January 1, 2010, in accordance with the 2008 Plan annual increase provisions, the authorized shares in the 2008 Plan increased by 1,064,279.

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 independent contractors of the Company. Options are granted with exercise prices equal to the fair value of the common stock on the date of the grant, as determined by the Company's Board of Directors. The terms of options may not exceed ten years. Generally, options vest over a four-year period.

Prior to 2005, the Board of Directors approved the grant of 75,971 stock options outside 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 the Company's acquisition of nura on August 11, 2006, the Company assumed all of the outstanding options issued under nura's 2003 Stock Plan (the nura Plan). As of December 31, 2009 and 2008, options to purchase 2,981 and 3,086 shares, respectively, of the Company's 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. The Company does not intend to issue any additional stock options pursuant to the nura Plan.

The Company accounts for cash received in consideration for the purchase of unvested shares of common stock or the early-exercise of unvested stock options as a current liability, included as a component of accrued liabilities in the Company's balance sheets. As of December 31, 2009 and 2008, there were 0 and 28,762 unvested shares of the Company's common stock outstanding, respectively, and \$0 and \$54,000, of related recorded liability, respectively, which is included in accrued liabilities.

F-30

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Table of Contents

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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, 2008	1,020,728	2,839,850	\$ 1.40		
Authorized increase in 2008 Plan shares	168,049				
Expired	(166,020)		1.75		
Repurchased	25,968		1.86		
Granted	(177,496)	177,496	10.59		
Exercised		(27,767)	1.53		
Cancelled	142,030	(142,030)	1.90		
Balance at December 31, 2009	1,013,259	2,847,549	\$ 1.94	6.83	\$ 15,276
Vested and expected to vest at December 31, 2009		2,785,595	\$ 1.82	6.79	\$ 15,173
Exercisable at December 31, 2009		2,391,784	\$ 1.19	6.53	\$ 14,019

Information about stock options outstanding and exercisable is as follows:

Range of Exercise Price	December 31, 2009				
	Options Number of Options	Options Outstanding Weighted- Average Remaining Contractual Life (Years)	Weighted- Average Exercise Price	Options Exercisable Number of Options	Weighted- Average Exercise Price
\$0.35-0.78	73,111	1.43	\$ 0.50	73,111	\$ 0.50
\$0.98	2,076,224	6.58	0.98	2,018,444	0.98
\$1.96-2.45	481,349	7.62	2.33	286,539	2.31
\$2.46-13.49	216,865	9.24	10.79	13,690	12.32



**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Expected Volatility.* 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.* The Company 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.* The Company has never declared or paid any cash dividends and does 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. The Company estimates forfeitures based on its historical experience; separate groups of employees that have similar historical forfeiture behavior are considered separately for expense recognition.

Stock options granted to non-employees are accounted for using the fair value approach. The fair value of non-employee option grants are estimated using the Black-Scholes option-pricing model and are re-measured over the vesting term as earned. The estimated fair value is charged to expense over the applicable service period. During the year ended December 31, 2007, the Company granted 80,475 options to non-employees to purchase shares of common stock. During the years ended December 31, 2009 and 2008 no options were granted to non-employees.

In conjunction with the exercise of certain stock options, the Company received nonrecourse promissory notes from Gregory A. Demopoulos, M.D., the Company's president, chief executive officer and chairman of the board of directors, totaling \$239,000. The promissory notes accrued interest at rates ranging from 3% to 6.25% and were secured by pledges of the underlying common stock. Since the notes were non-recourse, they were treated as stock options subject to variable accounting whereby changes in the estimated fair value of the underlying deemed option were reported as an increase or decrease, as applicable, in stock-based compensation expense until the notes were repaid in December 2007. Stock-based compensation expense relating to variable accounting for these notes was \$0, \$0, and \$5.0 million for the years ended December 31, 2009, 2008 and 2007, 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 the Company's consolidated statements of operations as follows:

	<b>Year Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
	<b>(in thousands)</b>		
Research and development	\$879	\$983	\$482
Table of Contents			205

General and administrative	615	1,332	5,574
Total	\$ 1,494	\$ 2,315	\$ 6,056

In connection with the non-employee options, the Company recognized expense of \$31,000, \$234,000 and \$119,000 during the years ended December 31, 2009, 2008 and 2007, respectively.

### **Note 13 Income Taxes**

The Company has a history of losses and therefore has 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

Table of Contents

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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:

	<b>2009</b>	<b>December 31,</b>	<b>2008</b>
	<b>(in thousands)</b>		
Deferred tax assets:			
Net operating loss carryforwards	\$ 30,925	\$	24,658
Deferred revenue	239		79
Stock-based compensation	130		120
Research and development tax credits	2,634		2,281
Other	117		133
	34,045		27,271
Less valuation allowance	(34,045)		(27,271)
Net deferred tax assets	\$	\$	

As of December 31, 2009 and 2008, the Company had net operating loss carryforwards of approximately \$90.9 million and \$72.5 million, respectively, and research and development tax credit carryforwards of approximately \$2.6 million and \$2.3 million, respectively. Unless previously utilized, the Company's net operating loss and research and development tax credit carryforwards will expire between 2010 and 2029. 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. 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). The Company's ability to utilize its 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.

A reconciliation of the Federal statutory tax rate of 34% to the Company's effective income tax rate follows:

	<b>2009</b>	<b>December 31,</b>	<b>2007</b>
	<b>(in thousands)</b>		
Statutory tax rate	(34)%	(34)%	(34)%
Permanent difference	4	6	9
Change in valuation allowance	20	21	20

Other	10	7	5
Effective tax rate			

The Company has established a 100% valuation allowance due to the uncertainty of the Company's ability to generate sufficient taxable income to realize the deferred tax assets. The Company's valuation allowance increased \$6.8 million, \$7.2 million and \$6.4 million in 2009, 2008 and 2007, respectively, primarily due to net operating losses incurred during these periods.

The Company files 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 the Company's tax years remain open to federal tax examination.

The guidance for accounting for uncertainties in income taxes requires that the Company 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, the



**Table of Contents**

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Company identified certain adjustments to its 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 and 2009. There were no unrecognized tax benefits that impacted the Company's effective tax rate and accordingly, there was no material effect to its financial position, results of operations or cash flows.

The Company's 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 the Company in relation to the underpayment of income taxes.

**Note 14 Related-Party Transactions**

The Company conducts research using the services of one of its founders, Pamela Pierce Palmer, M.D., Ph.D. Costs incurred for the years ended December 31, 2009, 2008 and 2007 totaled \$5,000 per year, and \$450,000 for the period of inception (June 16, 1994) through December 31, 2009. In 2007, the Company granted Dr. Palmer an option to purchase 20,408 shares of common stock and recognized \$(15,000), \$57,000 and \$42,000 of non-cash compensation associated with this option for the years ended December 31, 2009, 2008 and 2007, respectively, and \$84,000 for the period of inception (June 16, 1994) through December 31, 2009.

In conjunction with the exercise of certain stock options by Gregory A. Demopoulos, M.D., the Company received recourse notes totaling \$239,000 that were deemed to be non-recourse for accounting purposes. The notes were repaid in full in December 2007. The loans were secured by pledges of common stock of the Company. The loans bore interest ranging from 3% to 6.25%. Interest income on the loans totaled \$12,000 during each of the years ended December 31, 2007 and 2006. These notes were determined to be a variable stock compensation arrangement and the difference between the original exercise price of the related stock options and the fair value of the underlying common stock was recorded as stock compensation expense. For the year ended December 31, 2007 and for the period of inception (June 16, 1994) through December 31, 2009, \$5.0 million and \$5.6 million, respectively, has been recognized as stock compensation expense. The shares underlying the loans were not considered outstanding for the computation of basic and diluted net loss per common share.

In December 2007, the Company approved a payment to Dr. Demopoulos of \$159,000 as a tax gross-up amount related to payments that the Company made to him during 2007 that he used to repay his indebtedness to the Company in the amount of \$278,000, including principal and interest. The \$159,000 was recorded as an accrued liability as of December 31, 2007 and was subsequently paid by the Company to Dr. Demopoulos in January 2008.

**Note 15 401(k) Retirement Plan**

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

Table of Contents

**OMEROS CORPORATION**  
**(A Development Stage Company)**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Note 16 Quarterly Information (Unaudited)**

The following table summarizes the unaudited statements of operations for each quarter of 2009 and 2008 (in thousands except per share amounts):

	<b>March 31,</b>	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>
			<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)
			<b>2008</b>	
Revenue	\$ 234	\$ 254	\$ 501	\$ 181
Total operating expenses	5,766	5,151	8,165	6,613
Loss from operations	(5,532)	(4,897)	(7,664)	(6,432)
Net loss	(5,103)	(4,961)	(7,380)	(6,383)
Basic and diluted net loss per share	\$ (1.81)	\$ (1.72)	\$ (2.54)	\$ (2.19)

F-35

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

<b>Exhibit Number</b>	<b>Footnote Reference</b>	<b>Description</b>
2.1	(1)	Agreement and Plan of Reorganization among the registrant, Epsilon Acquisition Corporation, nura, inc. and ARCH Venture Corporation dated August 4, 2006
3.1		Amended and Restated Articles of Incorporation of Omeros Corporation
3.2		Amended and Restated Bylaws of Omeros Corporation
4.1	(2)	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	(3)	Form of Omeros Corporation Stock Purchase Warrant (as of December 31, 2009, warrants in this form permitted the purchase up to a total of 167,885 shares of common stock)
4.5	(3)	Form of Omeros Corporation Stock Purchase Warrant (as of December 31, 2009, warrants in this form permitted the purchase up to a total of 29,593 shares of common stock)
4.6	(3)	Form of Notice of Waiver of Warrant Termination (applicable to Stock Purchase Warrants filed as Exhibits 4.4 and 4.5)
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 (that does not permit early exercise)
10.4	(1)*	Form of Amendment to Stock Option Agreement under the Second Amended and Restated 1998 Stock Option Plan (to permit early exercise)
10.5	(1)*	Form of Stock Option Agreement under the Second Amended and Restated 1998 Stock Option Plan (that permits early exercise)
10.6	(1)*	nura, inc. 2003 Stock Plan
10.7	(1)*	Form of Stock Option Agreement under the nura, inc. 2003 Stock Plan
10.8	(4)*	2008 Equity Incentive Plan
10.9	(4)*	Form of Stock Option Award Agreement under the 2008 Equity Incentive Plan (used for option awards granted after October 7, 2009)
10.10	(4)*	Form of Stock Option Award Agreement under the 2008 Equity Incentive Plan (used for option awards granted on or before October 7, 2009 )
10.11	(1)*	Second Amended and Restated Employment Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated December 30, 2007
10.12	(1)*	Non-Plan Stock Option Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated December 11, 2001
10.13	(1)*	Offer Letter between Omeros Corporation and Marcia S. Kelbon, Esq. dated August 16, 2001
10.14	(1)*	Offer Letter between Omeros Corporation and Richard J. Klein dated May 11, 2007
10.15	(1)*	Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated June 16, 1994
10.16	(1)	Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated June 16, 1994
10.17	(1)*	

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- Second Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated December 11, 2001
- 10.18 (1) Second Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated March 22, 2002
- 10.19 (1)\* Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated June 16, 1994 (related to tendon splice technology)
- 10.20 (1) U.S. Bank Centre Office Lease Agreement between Bentall City Centre LLC and Scope International, Inc. dated September 28, 1998
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**Table of Contents**

10.21	(1)	Assignment and Amendment of Lease among Omeros Corporation, City Centre Associates and Navigant Consulting, Inc. dated August 1, 2002
10.22	(1)	Second Amendment to Office Lease Agreement between Omeros Corporation and City Centre Associates dated January 4, 2006
10.23	(1)	Lease Agreement between Alexandria Real Estate Equities, Inc. and Primal, Inc. dated April 6, 2000
10.24	(1)	Lease Agreement between Alexandria Real Estate Equities, Inc. and Primal, Inc. dated September 28, 2001
10.25	(1)	Assignment and Assumption and Modification of Lease Documents among Alexandria Real Estate Equities, Inc., Primal, Inc., and nura, inc. dated October 23, 2003
10.26	(1)	Assignment and Assumption and Modification of Lease Documents among Alexandria Real Estate Equities, Inc., nura, inc., and Omeros Corporation dated September 26, 2007
10.27	(3)	Commercial Supply Agreement between Omeros Corporation and Hospira Worldwide, Inc. dated October 9, 2007
10.28	(3)	Exclusive License and Sponsored Research Agreement between Omeros Corporation and the University of Leicester dated June 10, 2004
10.29	(1)	Research and Development Agreement First Amendment between Omeros Corporation and the University of Leicester dated October 1, 2005
10.30	(3)	Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005
10.31	(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
10.32	(5)	Funding Agreement between Omeros Corporation and The Stanley Medical Research Institute dated December 18, 2006
10.33	(5)	Drug Product Development and Clinical Supply Agreement between Omeros Corporation and Althea Technologies, Inc. dated January 20, 2006
10.34	(3)	Project Plan for Non-GMP and cGMP Fill and Finish of OMS302 between Omeros Corporation and Althea Technologies, Inc. dated May 31, 2007
10.35	(4)	Landlord Consent to Sublease among Christensen O Connor Johnson Kindness PLLC, City Centre Associates and Omeros Corporation dated January 29, 2008
10.36	(3)	Agreement for Antibody Discovery and Development between Omeros Corporation and Affitech AS dated July 25, 2008
10.37	(5)	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
10.38	(6)	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
10.39	(5)	Loan and Security Agreement between Omeros Corporation and BlueCrest Capital Finance, L.P. dated September 12, 2008
10.40	(5)	Promissory Note issued by Omeros Corporation to BlueCrest Capital Finance, L.P. dated September 12, 2008
10.41	(5)	Promissory Note issued by Omeros Corporation to BlueCrest Capital Finance, L.P. dated December 23, 2008
10.42	(3)	Agreement for Antibody Development between Omeros Corporation and North Coast Biologics LLC dated October 31, 2008
10.43	(3)	Patent Assignment Agreement between Omeros Corporation and Roberto Ciccocioppo, Ph.D. dated February 23, 2009

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10.44	(5)*	Amendment to Exercise Notice and Restricted Stock Purchase Agreements between the registrant and Richard J. Klein dated April 29, 2009
10.45	(3)*	Second Amendment to Exercise Notice and Restricted Stock Purchase Agreements between the registrant and Richard J. Klein dated July 28, 2009.
10.46	(3)*	Omeros Corporation Non-Employee Director Compensation Policy.

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**Table of Contents**

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 Registration Statement on Form S-1/A filed by Omeros Corporation on October 2, 2009 (File No. 333-148572).
- (3) Incorporated by reference from the Registration Statement on Form S-1/A filed by Omeros Corporation on September 16, 2009 (File No. 333-148572).
- (4) Incorporated by reference from the Registration Statement on Form S-1/A filed by Omeros Corporation on April 1, 2008 (File No. 333-148572).
- (5) Incorporated by reference from the Registration Statement on Form S-1/A filed by Omeros Corporation on May 15, 2009 (File No. 333-148572).
- (6) Incorporated by reference from the Current Report on Form 8-K filed by Omeros Corporation on November 12, 2009 (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.