OMEROS CORP
Form 10-K
March 31, 2010

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

FORM 10-K

(Mark One)

þ **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

o **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	**91-1663741**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
1420 Fifth Avenue, Suite 2600 **Seattle, Washington**	**98101**
(Address of principal executive offices)	(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	**The NASDAQ Stock Market LLC**
(Title of each class)	(Name of each exchange on which registered)

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

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

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 o No þ

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 þ No o

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 o No o

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. þ

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 o	Accelerated filer o
Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company o

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

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.

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

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PART I

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

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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 , 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 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 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 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.

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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.

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Our Product Candidates and Development Programs

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

Product Candidate/Program	Targeted Procedure/Disease	Development Status	Expected Near-Term Milestone (1)	Worldwide Rights
Clinical Programs				
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
Preclinical Programs				
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
GPCR Program	Multiple disorders	Platform	Surrogate de-orphanization of orphan 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

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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

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a complex reaction to tissue injury with multiple pathways, mechanisms and pro-inflammatory mediators, such as PGE2, involving three major components:

- alterations in vascular caliber, or vasodilation, that lead to an increase in blood flow;
- structural changes in the microvasculature that permit plasma proteins to leave the circulation, or plasma extravasation; and
- white cell migration from the microcirculation to the site of tissue injury.

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

Added to standard irrigation solutions, OMS103HP is delivered directly to the joint throughout arthroscopy, and is designed to act simultaneously at multiple distinct targets to block preemptively the inflammatory cascade induced by arthroscopic surgery. OMS103HP contains the following three 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 PGE2, and antagonizing the effects of bradykinin, another inflammatory mediator;
- *Amitriptyline* is a compound with analgesic activity that inhibits the pro-inflammatory actions of histamine and serotonin released locally at the site of tissue trauma; and
- *Oxymetazoline* is a vasoconstrictor and also activates serotonin receptors, located on a group of nerve fibers called primary afferents, that can inhibit the release of proinflammatory mediators such as substance P and calcitonin gene-related peptide, or CGRP.

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

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

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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

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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 ≥ 90° without Pain

*p = 0.016, log-rank

Figure 1 depicts the median number of days to maximum passive flexion ≥ 90° 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° of flexion of the operated knee. CPM machine usage was significantly less for OMS103HP.

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Figure 3: OMS103HP-Treated Patients Demonstrated Better Quadriceps Strength Testing at Day 30

*p = 0.040, FET

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

*p = 0.026, 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 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.*

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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

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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®, Acular®, Voltaren® and Xibrom®, 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®, 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.

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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.

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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.

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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-mydriatic 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-mydriatic 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

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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.

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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 , 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 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 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 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 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.

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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

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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.

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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

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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

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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.

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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.

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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.

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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

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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

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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.

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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;

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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

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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

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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;

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

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

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

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

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

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

Intellectual Property

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,

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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,

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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. Demopulos, 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. Demopulos, 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

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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

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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.

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The FDA regulates certain of our candidate products as combination drugs under its Combination Drug Policy because they are comprised of two or more active ingredients. The FDA s Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product s effectiveness.

In addition, we, our suppliers, and our contract manufacturers are required to comply with extensive FDA requirements both before and after approval. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotion for our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in all areas of regulatory compliance, including production and quality control to comply with cGMP. In addition, discovery of problems such as safety problems may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

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

Research and Development

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

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Executive Officers and Key Employees

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

Name	Age	Position(s)
Executive Officers:		
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
Key Employees:		
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 Nastech 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

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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 Lilli & 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.omeros.com. We make available, free of charge through our web site, our annual report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the 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.

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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.

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

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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[tm] 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

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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

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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;

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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

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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;

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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

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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

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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.

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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.

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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

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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.

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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.

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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 Demopulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, could delay execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

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

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

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

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

In December 2008, our former chief financial officer, Richard J. Klein, used our Whistleblower Policy procedures to report to the chairman of our audit committee that we had submitted grant reimbursement claims to the National Institutes of Health, or NIH, for work that we had not performed. In accordance with the Whistleblower Policy and its charter, our audit committee, with special outside counsel, commenced an independent investigation of our NIH grant

and claims procedures. The investigation concluded that we had not submitted claims to the NIH for work we had not performed. In January 2009, we terminated Mr. Klein s employment for reasons other than this incident. Mr. Klein alleged that he was wrongfully terminated and claimed it was retaliatory. We subsequently voluntarily reported to the NIH Mr. Klein s whistleblower report

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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

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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

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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

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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;

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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

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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

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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

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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:

2009	High	Low
4th 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.

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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:

Period		Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Program	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
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.

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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	2008	2007	2006	2005	2009
	(in thousands, except share data)					
Consolidated Statements of Operations Data:						
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

	As of December 31,				
	2009	**2008**	**2007**	**2006**	**2005**
Consolidated Balance Sheet Data:					
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)

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

The following discussion and analysis should be read in conjunction with our audited annual consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled Risk Factors and elsewhere in this Annual Report on Form 10-K. For further information regarding forward-looking statements, please refer to the special note regarding forward-looking statements at the end of Item 1 of this Annual Report on Form 10-K. Throughout this discussion, unless the context specifies or implies otherwise, the terms Company, we, us and our refer to Omeros Corporation and nura, inc., its wholly-owned subsidiary.

Overview

Background

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products 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

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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

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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:

	Years Ended December 31,		
	2009	2008	2007
	(in thousands)		
Clinical Research and Development			
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
Total Clinical Research and Development Expenses	10,587	10,765	9,430
Preclinical Research and Development			
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
Total Preclinical Research and Development Expenses	6,342	7,085	6,492
Total Research and Development Expenses	$ 16,929	$ 17,850	$ 15,922

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.

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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.

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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:

	December 31,		
	2009	**2008**	**2007**
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.

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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. 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 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.

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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.

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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.

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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.

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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

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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.

	Payments Due Within				
	1 Year	2-3 Years	4-5 Years	More than 5 Years	Total
			(in thousands)		
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
Total	$ 7,976	$ 9,755	$ 25	$ 40	$ 17,796

(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 dependi