

OMEROS CORP  
Form S-1/A  
June 23, 2009

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**As filed with the Securities and Exchange Commission on June 23, 2009**

**Registration No. 333-148572**

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

**AMENDMENT NO. 4 TO  
Form S-1**

**REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**Omeros Corporation**

*(Exact name of registrant as specified in its charter)*

**Washington**

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

**2834**

*(Primary Standard Industrial  
Classification Code Number)*

**91-1663741**

*(I.R.S. Employer  
Identification Number)*

**1420 Fifth Avenue, Suite 2600  
Seattle, Washington 98101  
(206) 676-5000**

*(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)*

**Gregory A. Demopulos, M.D.  
President, Chief Executive Officer,  
Chief Medical Officer and  
Chairman of the Board of Directors  
Omeros Corporation  
1420 Fifth Avenue, Suite 2600**

**Seattle, Washington 98101  
(206) 676-5000**

*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting  
company

(Do not check if a  
smaller reporting

company)

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is declared effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**Subject to Completion, Dated June 23, 2009**

**Omeros Corporation**

**Shares  
Common Stock**

This is the initial public offering of Omeros Corporation. We are offering \_\_\_\_\_ shares of our common stock. We anticipate that the initial public offering price will be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share. We have applied to list our common stock on the NASDAQ Global Market under the symbol OMER.

**Investing in our common stock involves risk. See Risk Factors beginning on page 11.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

	<b>Per Share</b>	<b>Total</b>
Public offering price	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds, before expenses, to Omeros Corporation	\$	\$

We have granted the underwriters the right to purchase up to \_\_\_\_\_ additional shares of common stock to cover over-allotments.

**Deutsche Bank Securities**

**Wedbush Pac Grow Life Sciences**

**Leerink Swann**

**Needham & Company, LLC**

The date of this prospectus is \_\_\_\_\_, 2009.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Except where the context requires otherwise, in this prospectus the Company, Omeros, we, us and our refer to Omeros Corporation, a Washington corporation, and, where appropriate, its subsidiary.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of shares of common stock and the distribution of this prospectus outside of the United States.

### Market Data

This prospectus contains market data regarding the healthcare industry that we obtained from Sharon O Reilly Consulting, or SOR Consulting, Thomson Healthcare, The Reimbursement Group and Insight Pharma Reports. The market data regarding the number of arthroscopic operations, including knee arthroscopy operations, performed in the United States in 2006 is from SOR Consulting. Ms. O Reilly is the founder of Medtech Insight, a market research firm

that she left in 2007. Medtech Insight did not provide any of the data used in this prospectus. The market data regarding the number of cataract and uroendoscopic operations performed in the United States in 2006 is from Thomson Healthcare. In addition, our conclusions regarding the potential reimbursement of our PharmacoSurgery™ product candidates are based on reports that we commissioned from The Reimbursement Group, or TRG. The data regarding the number of drugs that target G protein-coupled receptors is from Insight Pharma Reports. Although we believe that all of these reports and data are reliable, we have not independently verified any of this information.



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**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information you should consider in making your investment decision. You should read this summary together with the more detailed information, including our financial statements and the related notes, elsewhere in this prospectus. You should carefully consider, among other things, the matters discussed in Risk Factors.*

**Omeros Corporation**

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 the clinical outcomes of patients undergoing arthroscopic, ophthalmological, urological and other surgical and medical procedures. Our PharmacoSurgery platform is based on low-dose proprietary 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 four ongoing PharmacoSurgery clinical development programs: two in arthroscopy, one in ophthalmology and one in uroendoscopy. The most advanced of these, OMS103HP for use in arthroscopy, is in Phase 3 clinical trials. In addition to our PharmacoSurgery platform, we have leveraged our expertise in inflammation and the central nervous system, or CNS, to build a pipeline of preclinical programs targeting large markets. By combining our late-stage PharmacoSurgery product candidates with our deep and diverse pipeline of preclinical development programs, we believe that we create multiple opportunities for commercial success. For each of our product candidates and programs, we have retained all manufacturing, marketing and distribution rights.

**Our PharmacoSurgery Platform**

*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 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 systemically delivered, such as by oral or intravenous administration, to target these problems 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.

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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 patent portfolio covers all arthroscopic, ophthalmological, urological, cardiovascular and other types of surgical and medical procedures, and includes both method and composition claims broadly directed to combinations of agents drawn from distinct classes of therapeutic agents delivered to the procedural site intra-operatively, regardless of whether the agents are generic or proprietary. Our current PharmacoSurgery product candidates are specifically comprised of active pharmaceutical ingredients, or APIs, contained in generic drugs already approved by the U.S. Food and Drug Administration, or FDA, with established profiles of safety and pharmacologic activities, and are eligible for submission under the potentially less-costly and time-consuming Section 505(b)(2) New Drug Application, or NDA, process.

*Market Opportunity*

According to market data from SOR Consulting and Thomson Healthcare, approximately a total of: 4.0 million arthroscopic operations, including 2.6 million knee arthroscopy operations; 2.9 million cataract operations; and 4.3 million uroendoscopic operations were performed in the United States in 2006. We expect the number of these operations to grow as the population and demand for minimally invasive procedures increases and endoscopic technologies improve. In addition, based on reports that we commissioned from The Reimbursement Group, a reimbursement consulting firm, we anticipate that each of our current PharmacoSurgery product candidates will be favorably reimbursed both to the surgical facility and to the surgeon. As a result, we estimate that there are large markets for each of our PharmacoSurgery product candidates and believe that OMS103HP alone provides a multi-billion dollar market opportunity.

*Our Lead Product Candidate OMS103HP*

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. OMS103HP is a proprietary combination of APIs with known anti-inflammatory, analgesic and vasoconstrictive activities. 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 prescription drug products for over 15 years and have established and well-characterized safety profiles. We believe that OMS103HP will, if approved, be the first commercially available drug product for the improvement of function following arthroscopic surgery, and will, based on the data from our OMS103HP Phase 1/Phase 2 clinical program, provide additional postoperative clinical benefits, including improved range of motion, reduced pain and earlier return to work. 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).

OMS103HP selectively targets multiple and discrete pro-inflammatory mediators and pathways within the inflammatory and pain cascade. Added to standard irrigation solutions, OMS103HP is delivered to the joint at the initiation of surgical trauma to preemptively inhibit the inflammatory and pain cascade. Continuous 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



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procedure, systemic absorption of the APIs will be minimized or avoided, thereby reducing the risk of adverse side effects.

We expect to complete the Phase 3 clinical trials in patients undergoing ACL reconstruction surgery and, assuming positive results, intend to submit an NDA to the FDA under the Section 505(b)(2) process during the second half of 2010. In the second half of 2009, we expect to review the data from our first Phase 2 clinical trial in patients undergoing meniscectomy surgery.

### *Our Other PharmacoSurgery Product Candidates*

#### *OMS302*

OMS302 is our PharmacoSurgery product candidate being developed for use during ophthalmological procedures, including cataract and other lens replacement surgery. OMS302 is a proprietary combination of an anti-inflammatory API and an API that causes pupil dilation, or mydriasis, each with well-known safety and pharmacologic profiles. FDA-approved drugs containing each of these APIs have been used in ophthalmological clinical practice for more than 15 years, and both APIs are contained in generic, FDA-approved drugs.

OMS302 is added to standard irrigation solution used in cataract and other lens replacement surgery, and is delivered directly into the anterior chamber of the eye 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. 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. Patients treated with OMS302 reported less postoperative pain and demonstrated statistically significant improvement in maintenance of mydriasis compared to patients treated with vehicle control. There were no serious adverse events.

We are currently conducting a Phase 2 concentration-ranging clinical trial to assist in determining the optimal concentration of the mydriatic API contained in OMS302 in patients undergoing cataract surgery. We expect to complete this trial in mid-2009.

#### *OMS201*

OMS201 is our PharmacoSurgery product candidate being developed for use during urological surgery, including uroendoscopic procedures of the bladder, ureter, urethra and other urinary tract structures. OMS201 is a proprietary combination of an anti-inflammatory API and a smooth muscle relaxant API. Both APIs 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 delivered directly to the surgical site during uroendoscopic procedures, such as bladder endoscopy, minimally invasive prostate surgery and ureteroscopy, to inhibit surgically induced inflammation, pain and smooth muscle spasm, or excess contractility. We recently completed a Phase 1 clinical trial that evaluated the safety and systemic absorption of OMS201 added to standard irrigation solution and delivered to patients undergoing ureteroscopy for removal of ureteral or renal stones. The pharmacokinetic data from this clinical trial show that systemic plasma levels of the APIs of OMS201 in patients were minimal or below the level of quantification. There were no serious adverse events.

Based on the successfully completed Phase 1 clinical trial, we are now conducting a Phase 1/Phase 2 clinical trial to evaluate the efficacy, safety and systemic absorption of potentially two sequentially higher concentrations of OMS201, which we expect to complete in the first half of 2010.

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**Our Preclinical Development Programs**

*MASP-2 Program*

In our mannan-binding lectin-associated serine protease-2, or MASP-2, program, we are developing antibody therapies to treat disorders caused by complement activated inflammation. MASP-2 is a novel pro-inflammatory protein target in the complement system, an important component of the immune system. MASP-2 appears to be required for the function of the lectin pathway, one of the principal complement activation pathways. 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. We have generated several fully human, high-affinity, blocking antibodies to MASP-2, and from these or other antibodies expect to select a clinical product candidate in the second half of 2009.

*Addiction Program*

In our Addiction program, we are developing proprietary compositions that include peroxisome proliferator-activated receptor gamma, or PPAR $\gamma$ , agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine, alcohol and amphetamines, as well as other compulsive behaviors. Based on the previously unknown link between PPAR $\gamma$  and addictive disorders together with promising data from European pilot clinical studies and animal models of addiction, we have filed patent applications claiming the use of any PPAR $\gamma$  agonist, alone or in combination with other agents, for the treatment or prevention of addiction and other compulsive behaviors. We plan to submit an IND to the FDA in the second half of 2009 to evaluate a PPAR $\gamma$  agonist in combination drug product candidates.

*PDE10 Program*

In our Phosphodiesterase 10, or PDE10, program, we are developing compounds that inhibit PDE10 for the treatment of schizophrenia. 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 new anti-psychotic drugs. 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. From our proprietary preclinical product candidates we plan to select one or more clinical candidates in the second half of 2009 to advance into toxicology studies in preparation for clinical trials.

*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. Based on our promising preclinical data in a model of PD showing efficacy of PDE7 inhibitors equivalent to that of levodopamine, we are developing proprietary compounds for the treatment of movement disorders. Levodopamine 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.

*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



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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 227 non-orphans and 136 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. According to Insight Pharma Reports, 125, or greater than 50%, of the non-orphan GPCRs are either targeted by marketed drugs or drugs in development. Applying that same percentage to the 136 orphan GPCRs, 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.

## **Our 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 PharmacoSurgery product candidates OMS103HP, OMS302 and OMS201;

maximize commercial opportunity for our PharmacoSurgery product candidates OMS103HP, OMS302 and OMS201;

continue to leverage our business model to mitigate risk by combining our multiple late-stage PharmacoSurgery product candidates with our deep and diverse pipeline of preclinical development programs;

further expand our broad patent portfolio; and

manage our business with continued efficiency and discipline, while continuing to evaluate opportunities and acquire technologies that meet our business objectives.

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**Risks Related to our Business**

The risks set forth under the section entitled Risk Factors beginning on page 11 of this prospectus reflect risks and uncertainties that could significantly and adversely affect our business and our ability to execute our business strategy. For example:

We are largely dependent on the success of our PharmacoSurgery product candidates, particularly our lead product candidate, OMS103HP, and our clinical trials may fail to adequately demonstrate the safety and efficacy of OMS103HP or our other PharmacoSurgery product candidates. If a clinical trial fails, if regulatory approval is delayed or if additional clinical trials are required, our development costs may increase and we will not have the anticipated revenue from that product candidate to fund our operations.

We are a clinical-stage company with no product revenue and no products approved for marketing. The regulatory approval process is expensive, time-consuming and uncertain, and our product candidates have not been, and may not be, approved for sale by regulatory authorities. Even if approved for sale by the appropriate regulatory authorities, our products may not achieve market acceptance and we may never achieve profitability.

Our preclinical development programs may not generate product candidates that are suitable for clinical testing or that can be successfully commercialized.

Our patents may not adequately protect our present and future product candidates or permit us to gain or keep a competitive advantage. Our pending patents for our present and future product candidates may not be issued.

**Technology Development**

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 and our acquisition of nura, inc., a private biotechnology company. For instance, our scientific co-founders, Gregory A. Demopoulos, M.D. and Pamela Pierce Palmer, M.D., Ph.D., conceived the initial inventions underlying our PharmacoSurgery platform and have transferred all of their related intellectual property rights to us. Dr. Demopoulos is our president, chief executive officer, chief medical officer and chairman of our board of directors. We also require our employees to sign agreements with us pursuant to which they assign to us all inventions conceived by them in the course of their employment.

In addition, 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. Under the University of Leicester and MRC license agreements, we have agreed to pay royalties to each of the University of Leicester and MRC based on any proceeds that we receive from the licensed technology during the terms of these agreements. The term of each 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. We obtained the assets for our Addiction program in February 2009 pursuant to a Patent Assignment Agreement with Roberto Ciccocioppo, Ph.D. of the Università di Camerino. We have agreed to pay royalties and milestone payments to Dr. Ciccocioppo related to any products that are covered by the patents that we acquired from him. 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. We acquired our PDE10, GPCR and PDE7 programs and related patents and other intellectual property rights as a result of our acquisition of nura in August 2006. We hold an exclusive option to purchase the CRA for our GPCR

program from Patobios Limited for approximately \$10.8 million Canadian dollars, or CAD, payable in cash and our common stock. Our exclusive option with Patobios ends on December 4, 2009, provided that we have the right to extend our option for one additional six-month period ending June 4, 2010 by paying Patobios \$650,000 CAD.

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**Corporate Information**

We were incorporated as a Washington corporation on June 16, 1994. Our principal executive offices are located at 1420 Fifth Avenue, Suite 2600, Seattle, Washington 98101, and our telephone number is (206) 676-5000. Our web site address is [www.omerost.com](http://www.omerost.com). The information on, or that can be accessed through, our web site is not part of this prospectus.

Omeros<sup>®</sup>, the Omeros logo<sup>®</sup>, nura<sup>®</sup>, and PharmacoSurgery<sup>™</sup> are trademarks of Omeros Corporation in the United States and other countries. This prospectus also includes trademarks of other persons.

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**The Offering**

Shares of common stock offered by us	shares
Shares of common stock to be outstanding after this offering	shares
Use of proceeds	We plan to use the net proceeds of this offering to fund (1) the completion of our Phase 3 clinical trials for OMS103HP and the submission of the related NDA(s) to the FDA, (2) the launch and commercialization of OMS103HP, (3) the clinical development of OMS302 and OMS201, (4) the development of our pipeline of preclinical programs and (5) working capital, capital expenditures, repayment of debt, potential acquisitions of products or technologies and general corporate purposes. See Use of Proceeds.
Proposed NASDAQ Global Market symbol	OMER

The number of shares of common stock that will be outstanding after this offering is based on the number of shares outstanding at March 31, 2009, and excludes:

5,441,744 shares of common stock issuable upon the exercise of options outstanding at March 31, 2009, at a weighted-average exercise price of \$0.72 per share;

205,000 shares of common stock issuable upon exercise of options granted from April 1, 2009 to June 15, 2009, at a weighted-average exercise price of \$6.33 per share;

22,613 shares of common stock issuable upon exercise of warrants outstanding at March 31, 2009, which will not automatically terminate upon the closing of this offering, at a weighted-average exercise price of \$4.66 per share; and

2,121,855 shares of common stock available for future issuance under our 2008 Equity Incentive Plan.

*Unless otherwise indicated, all information in this prospectus assumes:*

*the automatic conversion of all outstanding shares of our convertible preferred stock into 22,567,407 shares of common stock, effective upon the closing of this offering;*

*the conversion of all outstanding warrants to purchase shares of our convertible preferred stock into warrants to purchase 409,578 shares of common stock, effective upon the closing of this offering, 387,030 of which must be exercised or will automatically terminate upon the closing of this offering;*

*the issuance of            shares of common stock assuming the cashless net exercise of warrants that will automatically terminate upon the closing of this offering based on the assumed initial public offering price of*

§ (the mid-point of the range set forth on the cover page of this prospectus); and

no exercise by the underwriters of their right to purchase additional shares of common stock to cover over-allotments, if any.

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The following tables summarize consolidated financial data regarding our business and should be read together with Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the related notes included elsewhere in this prospectus. The consolidated statements of operations data for the years ended December 31, 2008, 2007 and 2006 and for the period from June 16, 1994 (inception) to December 31, 2008 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations data for the three months ended March 31, 2009 and 2008 and for the period from June 16, 1994 (inception) to March 31, 2009, and the consolidated balance sheet data as of March 31, 2009 are derived from our unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements included in this prospectus and include, in the opinion of management, all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results to be expected in any future period, and the results for the three months ended March 31, 2009 are not necessarily indicative of the results to be expected for the full year ending December 31, 2009. We acquired nura, inc., or nura, on August 11, 2006, and the results of nura are included in the consolidated financial statements from that date. The pro forma basic and diluted net loss per common share data are computed using the weighted-average number of shares of common stock outstanding, after giving effect to the conversion (using the as if-converted method) of all shares of our convertible preferred stock into common stock.

	<b>Three Months Ended</b>		<b>Period from</b>	<b>Year Ended December 31,</b>			<b>Period</b>	
	<b>March 31,</b>	<b>March 31,</b>	<b>June 16,</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>from</b>	
	<b>2009</b>	<b>2008</b>	<b>June 16,</b>				<b>June 16,</b>	
			<b>1994</b>				<b>1994</b>	
			<b>(Inception)</b>				<b>(Inception)</b>	
			<b>to</b>				<b>to</b>	
			<b>March 31,</b>				<b>December 31</b>	
			<b>2009</b>				<b>2008</b>	
	<b>(in thousands, except share and per share data)</b>							
<b>Consolidated</b>								
<b>Statements of</b>								
<b>Operations Data:</b>								
Grant revenue	\$ 197	\$ 234	\$ 3,590	\$ 1,170	\$ 1,923	\$ 200	\$ 3,393	
Operating expenses:								
Research and								
development	4,022	4,170	66,256	17,850	15,922	9,637	62,234	
Acquired in-process								
research and								
development			10,891			10,891	10,891	
General and								
administrative	1,410	1,596	33,893	7,845	10,398	3,625	32,483	
Total operating								
expenses	5,432	5,766	111,040	25,695	26,320	24,153	105,608	
Loss from operations	(5,235)	(5,532)	(107,450)	(24,525)	(24,397)	(23,953)	(102,215)	

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Investment income	81	279	5,244	661	1,582	1,088	5,163
Interest expense	(590)	(22)	(1,219)	(335)	(151)	(91)	(629)
Other income (expense)	262	172	696	372	(125)	179	434
Net loss	\$ (5,482)	\$ (5,103)	\$ (102,729)	\$ (23,827)	\$ (23,091)	\$ (22,777)	\$ (97,247)
Basic and diluted net loss per common share	\$ (0.95)	\$ (0.92)		\$ (4.22)	\$ (5.44)	\$ (6.17)	
Weighted-average shares used to compute basic and diluted net loss per common share	5,740,914	5,522,711		5,651,583	4,248,212	3,694,388	
Pro forma basic and diluted net loss per common share (unaudited)	\$ (0.20)			\$ (0.84)			
Weighted-average pro forma shares used to compute pro forma basic and diluted net loss per common share (unaudited)	28,180,321			27,978,990			



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The pro forma consolidated balance sheet data in the table below reflect (a) the automatic conversion of all outstanding shares of our convertible preferred stock into 22,567,407 shares of our common stock upon the closing of this offering and (b) the automatic conversion of all outstanding warrants to purchase convertible preferred stock into warrants to purchase 409,578 shares of our common stock upon the closing of this offering, resulting in the reclassification of \$1.7 million from preferred stock warrant liability to shareholders' equity (deficit). The pro forma as adjusted consolidated balance sheet data in the table below further adjust the pro forma information to reflect (a) our sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share (the mid-point of the range set forth on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (b) the issuance of \_\_\_\_\_ shares of common stock assuming the cashless net exercise of warrants that will automatically terminate upon the closing of this offering based on the assumed initial public offering price.

	As of March 31, 2009		
	Actual	Pro Forma (in thousands)	Pro Forma As Adjusted (1)
<b>Consolidated Balance Sheet Data:</b>			
Cash, cash equivalents and short-term investments	\$ 16,818	\$ 16,818	
Working capital (deficit)	(6,261)	(6,261)	
Total assets	18,782	18,782	
Total notes payable	16,344	16,344	
Preferred stock warrant liability	1,720		
Convertible preferred stock	91,019		
Deficit accumulated during the development stage	(102,729)	(102,729)	
Total shareholders' equity (deficit)	(96,093)	(3,354)	

- (1) A \$1.00 increase (decrease) in the assumed public offering price of \$ \_\_\_\_\_ would increase (decrease) each of cash, cash equivalents and short-term investments, working capital, total assets and total shareholders' equity (deficit) by \$ \_\_\_\_\_, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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**RISK FACTORS**

*You should carefully consider the risks described below before making an investment decision. Our business, prospects, financial condition or operating results could be materially adversely affected by any of these risks, as well as other risks not currently known to us or that we currently deem immaterial. 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 prospectus, including our consolidated financial statements and the related notes, before deciding to purchase any shares of our common stock.*

**Risks Related to Our Product Candidates and Operations**

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

We are a biopharmaceutical company with no products approved for commercial sale and we have not generated any revenue from product sales. We have incurred, and will continue to incur, significant costs relating to the clinical development and commercialization of our lead product candidate, OMS103HP, for use during arthroscopic anterior cruciate ligament, or ACL, reconstruction surgery as well as arthroscopic meniscectomy surgery. We have not yet obtained regulatory approval to market this product candidate for ACL reconstruction surgery, arthroscopic meniscectomy surgery or any other indication in any jurisdiction and we may never be able to obtain approval or, if approvals are obtained, to commercialize this product candidate successfully. If OMS103HP does not receive regulatory approval for ACL reconstruction surgery or arthroscopic meniscectomy surgery, 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 currently conducting a Phase 2 concentration-ranging clinical trial to assist in determining the optimal concentration of the mydriatic agent contained in OMS302 in patients undergoing cataract surgery. 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



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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 \$5.5 million, \$23.8 million, \$23.1 million and \$22.8 million for the three months ended March 31, 2009 and for the years ended December 31, 2008, 2007 and 2006, respectively. As of March 31, 2009, we had an accumulated deficit of approximately \$102.7 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. In addition, the audit report covering our 2008 consolidated financial statements contains an explanatory paragraph stating that our recurring losses and negative cash flows from operations, due to our negative working capital prior to the successful completion of this offering, raise substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will eliminate this doubt and enable us to continue as a going concern; however, if we are unable to raise sufficient capital in this offering, we will need to obtain alternative financing or significantly modify our operational plans for us to continue as a going concern.

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



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matters, and our views may, at times, differ from those of the FDA. For example, the FDA has questioned whether our studies evaluating OMS103HP in patients undergoing ACL reconstruction surgery are adequately designed to evaluate efficacy. If these studies fail to demonstrate efficacy, we will be required to provide additional information, including possibly the results of additional clinical trials. Also, the FDA regulates those of our product candidates consisting of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's effectiveness. The FDA has questioned the means by which we intend to demonstrate such contribution and whether available data and information demonstrate contribution for each active ingredient in OMS103HP. If we are unable to resolve these questions, we may be required to provide additional information, which may include the results of additional preclinical studies or clinical trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate for regulatory approval, if we are unable to successfully complete our clinical trials or other testing, or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may be delayed in obtaining marketing approval for our product candidates, or may never be able to obtain marketing approval.

Even if regulatory approval of a product candidate is obtained, such approval may be subject to significant limitations on the indicated uses for which that product may be marketed, conditions of use, and/or significant post approval obligations, including additional clinical trials. These regulatory requirements may, among other things, limit the size of the market for the product. Even after approval, discovery of previously unknown problems with a product, manufacturer, or facility, such as previously undiscovered side effects, may result in restrictions on any product, manufacturer, or facility, including, among other things, a possible withdrawal of approval of the product.

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

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory agencies, institutional review boards or us to delay our clinical trials or suspend or delay the analysis of the data from those trials. Clinical trials can be delayed for a variety of reasons, including:

discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;

delays or the inability to obtain required approvals from institutional review boards 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;



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- 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;
- 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 institutional review boards 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;
- initiate, conduct and complete the Phase 3 clinical trials of OMS103HP for use in arthroscopic meniscectomy surgery;
- 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;

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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 raise in this offering to complete the clinical development and commercialization of OMS103HP and to decrease spending on our other clinical and preclinical development programs. We have no commitments for additional 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 as further described 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 relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves. 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 or to immediately cease operations. 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. Although we believe that the breadth of our clinical and preclinical programs makes it unlikely that any single event would impact our viability, BlueCrest could nonetheless declare a



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default upon the occurrence of any event that it interprets as having a material adverse effect upon us as defined under our agreement, thereby requiring us 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;
- 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 institutional review board. 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

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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. For example, we engaged Scottish Biomedical, Ltd., or SBM, to assist us in developing compounds for our PDE10 and PDE7 programs. We believe that, among other things, SBM breached its obligations under our agreement and committed fraud, requiring us to re-perform certain services provided by SBM and delaying the advancement of our programs.

**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

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 have been 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. OSO announced that it intends to continue the 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



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reasonable terms. Qualification of any other facility to manufacture lyophilized OMS103HP would require transfer of manufacturing methods, the production of an additional registration batch 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 and may require us to conduct additional studies, which we expect would be nonclinical and/or clinical pharmacokinetic studies, to demonstrate that liquid OMS103HP is as safe and effective as lyophilized OMS103HP. Delays or unexpected results in these studies could delay the commercial availability of liquid OMS103HP. Any significant delays in the manufacture of clinical or commercial supplies could materially harm our business and prospects.

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

Contract manufacturers that we select to manufacture our product candidates for clinical testing or for commercial use may encounter difficulties with the small- and large-scale formulation and manufacturing processes required for such manufacture. These difficulties could result in delays in clinical trials, regulatory submissions, or commercialization of our product candidates. Once a product candidate is approved and being marketed, these difficulties could also result in the later recall or withdrawal of the product from the market or failure to have adequate supplies to meet market demand. Even if we are able to establish additional or replacement manufacturers, identifying these sources and entering into definitive supply agreements and obtaining regulatory approvals may require a substantial amount of time and cost and such supply arrangements may not be available on commercially reasonable terms, if at all.

In addition, we and our contract manufacturers must comply with current good manufacturing practice, or cGMP, requirements strictly enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. We or our contract manufacturers may be unable to comply with cGMP requirements or with other FDA, state, local and foreign regulatory requirements. We have little control over our contract manufacturers' compliance with these regulations and standards or with their quality control and quality assurance procedures but we are responsible for their compliance. Large-scale manufacturing processes have been developed only for lyophilized OMS103HP. For the liquid formulation of OMS103HP and our other product candidates, development of large-scale manufacturing processes will require validation studies, which the FDA must review and approve. Failure to comply with these requirements by our contract manufacturers could result in the issuance of untitled letters and/or warning letters from authorities, as well as sanctions being imposed on us, including fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product candidate supplied by contract manufacturers is compromised due to their failure to adhere to applicable laws or for other reasons, we may not be able to obtain or maintain regulatory approval for or successfully commercialize one or more of our product candidates, which would harm our business and prospects significantly.



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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 are likely to use proprietary active ingredients in some product candidates that we develop from our PDE7 program and possibly 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 programs. If we are unable to access rights to these active ingredients prior to preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, we may not be able to commercialize product candidates from these programs.

### **Our 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



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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 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 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, Addiction, 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. 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. Although we believe that we have the capability to de-orphanize orphan GPCRs, we have not yet attempted to do so. When we do attempt to de-orphanize orphan GPCRs, 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, such as OMS103HP, OMS302 and OMS201, 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



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requirements for patentability is a subjective determination based on the application of law and jurisprudence. For example, in the United States, a determination of patentability by the USPTO or validity by a court or other trier of fact requires a determination that the claimed invention has utility and is both novel and non-obvious to those of ordinary skill in the art in view of prior known publications and public information, and that the patent specification supporting the claim adequately describes the claimed invention, discloses the best mode known to the inventors for practicing the invention, and discloses the invention in a manner that enables one of ordinary skill in the art to make and use the invention. 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.

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We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

Further, a third party may claim that we or our contract manufacturers are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in the alleged infringing activity, including making, using or selling our 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 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 product candidates. 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



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publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents, our licensors' patents, our pending applications or our licensors' pending applications, or that we or our licensors were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technologies similar to ours. Any such patent application may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the capital necessary to continue our operations.

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

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

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

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies except for on the life of Gregory Demopoulos, M.D., our president, chief executive officer, chief medical officer and chairman of the board of directors. We have agreed to enter into a new employment agreement with Dr. Demopoulos by May 1, 2009. Although we have not yet entered into a new employment agreement with Dr. Demopoulos, we and Dr. Demopoulos intend to do so. If we are unable to enter into a new agreement with Dr. Demopoulos because of our actions or omissions, he could claim that we are in material breach of his current employment agreement, which may entitle Dr. Demopoulos to severance benefits described below in Management Executive Compensation Potential Payment upon Termination or Change in Control. 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.

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**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. In this regard, in anticipation of increased development and commercialization activities, we plan to increase the total number of our full-time employees from 67 as of May 31, 2009 to approximately 75 to 85 by the end of 2009. 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.

**We will 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 will 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 recently adopted corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new 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 new 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. As a public company, 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



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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 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. Other pharmaceutical companies, many with significantly greater resources than we have, are also developing PDE10 inhibitors for the treatment of schizophrenia 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. 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,

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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 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

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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 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.





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**Risks Related to the Offering**

**An active, liquid and orderly trading market for our common stock may not develop.**

Prior to this offering, there has been no public market for shares of our common stock. We and the representative of the underwriters will determine the initial public offering price of our common stock through negotiation. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. In addition, the trading price of our common stock following this offering is likely 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 Phase 2 clinical trial for OMS103HP for use in meniscectomy surgery, our ongoing Phase 2 clinical trial for OMS302, and our ongoing Phase 1/Phase 2 clinical trial for OMS201;

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;

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 shortly

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following this offering. 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.

**Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.**

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock immediately after this offering. Therefore, if you purchase our common stock in this offering, you will incur an immediate dilution of \$ [redacted] in net tangible book value per share from the price you paid, based on an assumed initial public offering price of \$ [redacted] per share (the mid-point of the range set forth on the cover page of this prospectus). In addition, investors who purchase shares in this offering will contribute approximately [redacted] % of the total amount of equity capital raised through the date of this offering, but will only own approximately [redacted] % of the outstanding share capital and approximately [redacted] % of the voting rights. The exercise of outstanding options and warrants will result in further dilution. For a further description of the dilution that you will experience immediately after this offering, see "Dilution."

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

If our existing shareholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on shares outstanding as of March 31, 2009, upon completion of this offering, we will have outstanding a total of [redacted] shares of common stock, assuming the issuance of [redacted] shares of common stock assuming the cashless net exercise of warrants that will automatically terminate upon the closing of this offering based on the assumed initial public offering price of \$ [redacted] (the mid-point of the range set forth on the cover page of this prospectus) and no exercise of the underwriters' over-allotment option. Of these shares, only the shares of common stock sold in this offering by us will be freely tradable, without restriction, in the public market. The representative of the underwriters may, in its sole discretion, release our officers, directors and other current shareholders from these contractual lock-up agreements prior to the expiration of these agreements.

We expect that the lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus, although those lock-up agreements may be extended for up to an additional 34 days under certain circumstances. After the lock-up agreements expire, up to an additional [redacted] shares of common stock will be eligible for sale in the public market, [redacted] of which shares of common stock are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements. In addition, [redacted] shares of common stock that are either subject to outstanding warrants that will not automatically terminate upon completion of this offering 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.

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**Anti-takeover provisions in our charter documents and under Washington law could make an acquisition of us, which may be beneficial to our shareholders, more difficult and prevent attempts by our shareholders to replace or remove our current management.**

Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of shareholders to fill board vacancies and the ability of our board of directors to issue preferred stock without shareholder approval. In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of shareholders owning ten percent or more of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

**We have broad discretion in the use of the net proceeds from this offering and may not use the net proceeds effectively.**

We will have broad discretion in the application of the net proceeds from this offering and 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.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus includes forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words believe, may, will, estimate, continue, anticipate, intend, expect and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Risk Factors. In light of these risks, uncertainties and assumptions, the forward-looking events and trends discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Forward-looking statements in the prospectus include statements about:

our ability to complete the Phase 3 clinical trials of OMS103HP in patients undergoing ACL reconstruction surgery and to submit a related NDA to the FDA during the second half of 2010;

our ability to review the data from our first Phase 2 trial of OMS103HP in patients undergoing arthroscopic meniscectomy surgery in the second half of 2009;

our ability to market OMS103HP by 2011;

our ability to complete the Phase 2 clinical trial for OMS302 in patients undergoing cataract surgery in mid-2009;

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

our ability to achieve the expected near-term milestones in our pipeline of preclinical development programs, including the selection of a clinical product candidate for our MASP-2 program in the second half of 2009, submission of an IND to the FDA for our Addiction program in the second half of 2009 and the selection of one or more clinical product candidates for our PDE10 program in the second half of 2009, and the size of target markets;

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, in particular, the market opportunity for OMS103HP, 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;

our expectations regarding the clinical benefits of our PharmacoSurgery product candidates;

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, along with the net proceeds from this offering, will be sufficient to fund our anticipated operating expenses and capital expenditures, the factors impacting our future

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capital expenditures and our expected number of full-time employees by the end of 2009;

our expectations regarding our ability to de-orphanize orphan GPCRs and the number of druggable targets among the orphan GPCRs;

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

our estimates regarding the use of the net proceeds from this offering and our future net losses, revenues, expenses and net operating loss carryforwards and research and development tax credit carryforwards.

You should read this prospectus and the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. These forward-looking statements represent our estimates and assumptions only as of the date of this prospectus and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended.



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**USE OF PROCEEDS**

We estimate that we will receive net proceeds of approximately \$ [redacted] from our sale of shares of common stock in this offering, or approximately \$ [redacted] if the underwriters exercise their over-allotment option in full, based upon an assumed initial public offering price of \$ [redacted] per share (the mid-point of the range set forth on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ [redacted] per share would increase (decrease) the net proceeds to us from this offering by \$ [redacted], assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We anticipate that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will allow us to complete our Phase 3 clinical trials and to submit the related NDA(s) for our lead PharmacoSurgery product candidate, OMS103HP. We currently expect to use the net proceeds from this offering as follows:

approximately \$ [redacted] to fund the completion of our clinical trials and our submission of the related NDA(s) to the FDA for our lead PharmacoSurgery product candidate, OMS103HP;

approximately \$ [redacted] to fund the launch and commercialization of OMS103HP;

approximately \$ [redacted] to fund the clinical development of our other PharmacoSurgery product candidates, OMS302 and OMS201, through Phase 2 clinical trials; and

the remainder to continue to fund our pipeline of preclinical product development programs focused on inflammation and CNS disorders, and to fund working capital, capital expenditures, potential acquisitions of products or technologies and general corporate purposes.

We may use a portion of the net proceeds for the repayment of a \$17.0 million loan and related interest pursuant to the terms of a Loan and Security Agreement with BlueCrest Venture Finance Master Fund Limited, assignee of BlueCrest Capital Finance, L.P., dated as of September 12, 2008. We borrowed the \$17.0 million in three tranches, one \$5.0 million tranche in September 2008 and two \$6.0 million tranches in December 2008. The proceeds of this borrowing have been used for working capital and general corporate activities. Our obligations under the agreement are secured by a first priority security interest in our assets excluding intellectual property. We are required to pay only interest on amounts borrowed during the first three months, and thereafter the amount borrowed is amortized over 36 months with equal monthly principal and interest payments. The interest rate of the debt is 12.50%. We have the right to prepay the principal amount of the loan in whole, but not in part, upon 30 days advance written notice to BlueCrest. If we prepay the loan, we will be required to pay BlueCrest a prepayment premium equal to two percent of the principal amount of any part of the loan that has been outstanding for 18 months or less and one percent for any amount that has been outstanding for more than 18 months. In connection with this financing arrangement, we are obligated to pay a one-time fee to BlueCrest in the amount of \$340,000 upon closing of this offering.

We may also use a portion of the net proceeds from this offering to purchase assets for our GPCR program pursuant to the terms of an Exclusive Technology Option Agreement with Patobios Limited. Under this agreement, we have the right to purchase Patobios' assets related to a GPCR assay technology, comprised of patents and other intellectual property rights, for approximately \$10.8 million Canadian dollars, or 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, we paid Patobios a \$200,000 CAD cash option fee (\$188,000 USD) for the right to test and exclusive option to purchase the assets during the

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nine-month period ending June 4, 2009. On June 12, 2009 we paid Patobios an additional \$522,000 CAD cash option fee (\$471,000 USD) to extend the option period until December 4, 2009. We have the option to extend this period for one additional six-month period ending June 4, 2010 by paying Patobios a cash option fee of \$650,000 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. In addition, if during an option period we identify a set of molecules, or ligands, that binds to an orphan GPCR using the assay technology, Patobios will have the option to require us to purchase these assets for the same price we would be required to pay if we elected to purchase them. While we are currently evaluating the utility of these assets for our GPCR program, we are not required to and are not currently attempting to identify any ligands that bind to an orphan GPCR using the assay technology.

The expected uses of the net proceeds from this offering represents our current intentions based on our present plans and business conditions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received from this offering. The amounts and timing of our actual expenditures will depend on numerous factors including the progress in, and costs of, our clinical trials and other preclinical development programs. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgement of management regarding the application of the net proceeds from the offering. We may find it necessary or advisable to use the net proceeds for other purposes. Pending such uses set forth above, we plan to invest the net proceeds in highly liquid, investment grade securities.

**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock, we do not currently intend to pay any cash dividends on our common stock in the foreseeable future 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. Any future determination to pay dividends, if any, on our common stock will be at the discretion of our board of directors and will depend on, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

**Table of Contents****CAPITALIZATION**

The following table sets forth our cash, cash equivalents and short-term investments and our capitalization as of March 31, 2009, as follows:

on an actual basis;

on a pro forma basis reflecting (a) the automatic conversion of all outstanding shares of our convertible preferred stock into 22,567,407 shares of our common stock upon the closing of this offering and (b) the automatic conversion of all outstanding warrants to purchase convertible preferred stock into warrants to purchase 409,578 shares of our common stock upon the closing of this offering, resulting in the reclassification of \$1.7 million from preferred stock warrant liability to additional paid-in capital;

on a pro forma as adjusted basis to give effect (a) to the issuance and sale by us of        shares of common stock in this offering and the receipt of the net proceeds from our sale of these shares at an assumed initial public offering price of \$        per share (the mid-point of the range set forth on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (b) to the issuance of        shares of common stock assuming the cashless net exercise of warrants that will automatically terminate upon the closing of this offering based on the assumed initial public offering price.

You should read this table together with the sections of this prospectus entitled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	<b>As of March 31, 2009</b>		
	<b>Actual</b>	<b>Pro Forma</b>	<b>Pro Forma As Adjusted</b>
	<b>(in thousands, except share and per share data)</b>		
Cash, cash equivalents and short-term investments	\$ 16,818	\$ 16,818	\$
Total notes payable	\$ 16,344	\$ 16,344	
Preferred stock warrant liability	1,720		
Convertible preferred stock; Issued and outstanding shares 22,567,407 (0 pro forma and pro forma as adjusted)	91,019		
Shareholders' equity (deficit):			
Preferred stock, par value \$0.01 per share; Authorized shares 26,314,511 (20,000,000 pro forma and pro forma as adjusted; issued and outstanding shares 0 pro forma and pro forma as adjusted)			
Common stock, par value \$0.01 per share; Authorized shares 40,000,000 (150,000 pro forma and        pro forma as adjusted); issued and outstanding shares 5,787,899 (28,355,306 pro	57	284	

forma and pro forma as adjusted)			
Additional paid-in capital	6,586	99,098	
Accumulated other comprehensive loss	(7)	(7)	
Deficit accumulated during the development stage	(102,729)	(102,729)	
Total shareholders equity (deficit)	(96,093)	(3,354)	
Total capitalization	\$ 12,990	\$ 12,990	\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) each of cash, cash equivalents and short-term investments,

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additional paid-in capital, total shareholders' equity (deficit) and total capitalization by \$ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The outstanding share information set forth in the table above excludes the following shares:

5,441,744 shares of common stock issuable upon the exercise of options outstanding at March 31, 2009, at a weighted-average exercise price of \$0.72 per share;

205,000 shares of common stock issuable upon exercise of options granted from April 1, 2009 to June 15, 2009, at a weighted-average exercise price of \$6.33 per share;

22,613 shares of common stock issuable upon exercise of warrants outstanding at March 31, 2009, which will not automatically terminate upon the closing of this offering, at a weighted-average exercise price of \$4.66 per share; and

2,121,855 shares of common stock available for future issuance under our 2008 Equity Incentive Plan.

**Table of Contents****DILUTION**

If you invest in our common stock, your interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value as of March 31, 2009 was \$(96.1) million, or \$(16.61) per share of common stock. Our pro forma net tangible book value as of March 31, 2009 was \$3.4 million, or \$(0.12) per share of common stock. Our pro forma net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of March 31, 2009, after giving effect (a) to the automatic conversion of all outstanding shares of our convertible preferred stock into common stock upon the closing of this offering and (b) to the automatic conversion of all outstanding warrants to purchase convertible preferred stock into warrants to purchase common stock upon the closing of this offering, 387,030 of which must be exercised or will automatically terminate upon closing of this offering.

After giving effect (a) to our issuance and sale in this offering of \_\_\_\_\_ shares of common stock at an assumed initial public offering price of \$ \_\_\_\_\_ per share (the midpoint of the range set forth on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and (b) to the issuance of \_\_\_\_\_ shares of common stock assuming the cashless net exercise of warrants that will automatically terminate upon the closing of this offering based on the assumed initial public offering price, our pro forma net tangible book value as of March 31, 2009 would have been approximately \$ \_\_\_\_\_, or \$ \_\_\_\_\_ per share of common stock. This represents an immediate increase in pro forma net tangible book value of \$ \_\_\_\_\_ per share to our existing shareholders and an immediate dilution of \$ \_\_\_\_\_ per share to investors purchasing shares in this offering. The following table illustrates this per share dilution:

Assumed initial public offering price per share	\$
Historical net tangible book value per common share at March 31, 2009	\$ (16.61)
Pro forma increase in net tangible book value per common share attributable to conversion of all outstanding convertible preferred stock into common stock and the reclassification of the preferred stock warrant liability to additional paid-in capital	(16.49)
Pro forma net tangible book value per share as of March 31, 2009	(0.12)
Pro forma increase in net tangible book value per share attributable to investors participating in this offering	
Pro forma net tangible book value per share after this offering	
Dilution in pro forma net tangible book value per share to investors purchasing shares in this offering	\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) our pro forma net tangible book value per share after this offering by \$ \_\_\_\_\_ and the dilution in pro forma net tangible book value per share to investors purchasing shares in this offering by \$ \_\_\_\_\_, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their over-allotment option in full, at an assumed initial public offering price of \$     per share, the pro forma net tangible book value per share after this offering would be approximately \$     per share, and the dilution in pro forma net tangible



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book value per share to investors purchasing shares in this offering would be approximately \$      per share.

The following table sets forth on an as adjusted basis, as of March 31, 2009, the number of shares of common stock purchased or to be purchased from us, the total consideration paid or to be paid and the average price per share paid or to be paid by existing holders of common stock and by the new investors purchasing shares in this offering, before deducting estimated underwriting discounts and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing shareholders	28,355,306	%	\$ 92,051,000	%	\$ 3.25
Holders of warrants exercised at closing					
New investors					
Total		%	\$	%	\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$      per share would increase (decrease) total consideration paid by new investors by \$      , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their over-allotment option in full, our existing shareholders would own      % and our new investors would own      % of the total number of shares of our common stock outstanding after this offering.

The discussion and tables above are based on the number of shares of common stock outstanding at March 31, 2009. The discussion and tables above exclude the following shares:

5,441,744 shares of common stock issuable upon the exercise of options outstanding at March 31, 2009, at a weighted-average exercise price of \$0.72 per share;

205,000 shares of common stock issuable upon the exercise of options granted from April 1, 2009 to June 15, 2009, at a weighted-average exercise price of \$6.33 per share;

22,613 shares of common stock issuable upon exercise of warrants outstanding at March 31, 2009, which will not automatically terminate upon the closing of this offering, at a weighted-average exercise price of \$4.66 per share; and

2,121,855 shares of common stock available for future issuance under our 2008 Equity Incentive Plan.

To the extent outstanding options or warrants are exercised, new investors will experience further dilution.

**Table of Contents****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 prospectus. The consolidated statements of operations data for the years ended December 31, 2008, 2007 and 2006 and for the period from June 16, 1994 (inception) to December 31, 2008, and the consolidated balance sheet data as of December 31, 2008 and 2007 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of operations data for the years ended December 31, 2005 and 2004, and the consolidated balance sheet data as of December 31, 2006, 2005 and 2004 are derived from our consolidated financial statements not included in this prospectus. The consolidated statements of operations data for the three months ended March 31, 2009 and 2008 and for the period from June 16, 1994 (inception) to March 31, 2009, and the consolidated balance sheet data as of March 31, 2009 are derived from our unaudited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements included in this prospectus and include, in the opinion of management, all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results to be expected in any future period, and the results for the three months ended March 31, 2009 are not necessarily indicative of the results to be expected for the full year ending December 31, 2009. We acquired nura on August 11, 2006, and the results of nura are included in the consolidated financial statements from that date. The pro forma basic and diluted net loss per common share data are computed using the weighted-average number of shares of common stock outstanding, after giving effect to the conversion (using the as if-converted method) of all shares of our convertible preferred stock into common stock.

Three Months		Period from June 16, 1994 (inception) to March 31, 2009		Years Ended December 31,			
Ended March 31, 2009	2008	2009	2008	2007	2006	2005	2004
(in thousands, except share and per share data)							
\$ 197	\$ 234	\$ 3,590	\$ 1,170	\$ 1,923	\$ 200	\$	\$
4,022	4,170	66,256	17,850	15,922	9,637	5,803	2,670
		10,891			10,891		
1,410	1,596	33,893	7,845	10,398	3,625	1,904	2,079
5,432	5,766	111,040	25,695	26,320	24,153	7,707	4,749

ations	(5,235)	(5,532)	(107,450)	(24,525)	(24,397)	(23,953)	(7,707)	(4,749)
me	81	279	5,244	661	1,582	1,088	333	171
e	(590)	(22)	(1,219)	(335)	(151)	(91)		
	262	172	696	372	(125)	179	8	
\$	(5,482)	\$ (5,103)	\$ (102,729)	\$ (23,827)	\$ (23,091)	\$ (22,777)	\$ (7,366)	\$ (4,578)
ed net								
n	\$ (0.95)	\$ (0.92)		\$ (4.22)	\$ (5.44)	\$ (6.17)	\$ (2.12)	\$ (1.34)
ge								
nd								
per	5,740,914	5,522,711		5,651,583	4,248,212	3,694,388	3,468,886	3,416,197
and								
per	\$ (0.20)			\$ (0.84)				
ge								
s								
e								
and								
per	28,180,321			27,978,990				

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	<b>As of March 31, 2009</b>	<b>2008</b>	<b>As of December 31,</b>			
			<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>
			<b>(in thousands)</b>			
<b>Consolidated Balance Sheet Data:</b>						
Cash, cash equivalents and short-term investments	\$ 16,818	\$ 19,982	\$ 24,082	\$ 35,885	\$ 12,372	\$ 14,008
Working capital (deficit)	(6,261)	(3,083)	16,526	32,277	10,672	13,664
Total assets	18,782	21,681	27,162	38,432	13,109	14,600
Total notes payable	16,344	16,674	1,010	2,015		
Preferred stock warrant liability	1,720	1,780	1,562	1,037	483	
Convertible preferred stock	91,019	89,168	89,168	85,742	40,888	35,203
Deficit accumulated in the development stage	(102,729)	(97,247)	(73,420)	(50,329)	(27,553)	(20,187)
Total shareholders deficit	(96,093)	(91,166)	(69,941)	(53,363)	(29,743)	(21,114)
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**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 and unaudited interim consolidated financial statements and the related notes that appear elsewhere in this prospectus. 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 prospectus.*

**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 four ongoing PharmacoSurgery clinical development programs, the most advanced of which is in Phase 3 clinical trials. In addition to our PharmacoSurgery platform, we have leveraged our expertise in inflammation and the central nervous system, or CNS, to build a deep and diverse pipeline of preclinical programs targeting large markets. 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 complete the Phase 3 clinical program for ACL reconstruction surgery and, assuming positive results, intend to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, under the Section 505(b)(2) NDA process during the second half of 2010. We believe that OMS103HP will, if approved, be the first commercially available drug product for the improvement of function following arthroscopic surgery. In the second half of 2009, we expect to review the data from our first Phase 2 clinical trial in patients undergoing meniscectomy 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, and we are currently conducting a Phase 2 concentration-ranging clinical trial of the mydriatic agent contained in OMS302 in patients undergoing cataract surgery and a Phase 1/Phase 2 clinical trial of OMS201 in patients undergoing ureteroscopic removal of ureteral or renal stones. We own and exclusively control a U.S. and international portfolio of issued patents and pending patent applications that we believe protects our PharmacoSurgery platform.



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In addition to our PharmacoSurgery platform, we have a deep and diverse pipeline of preclinical product development programs targeting large market opportunities in inflammation and the CNS covered by a broad intellectual property portfolio. 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 CNS pipeline includes our Addiction program, our Phosphodiesterase 10, or PDE10, program, our PDE7 program and our G protein-coupled receptors, or GPCR, program. In our Addiction program, we are developing proprietary compositions that include peroxisome proliferator-activated receptor gamma agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine, alcohol and amphetamines, as well as other compulsive behaviors. In our PDE10 program, we are developing proprietary compounds to treat schizophrenia. 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 March 31, 2009, our accumulated deficit was \$102.7 million and total shareholders' deficit was \$96.1 million. We recognized net losses of \$5.5 million, \$23.8 million, \$23.1 million and \$22.8 million for the three months ended March 31, 2009 and the years ended December 31, 2008, 2007 and 2006, respectively. These losses have resulted principally from expenses incurred in connection with research and development activities, consisting primarily of preclinical studies, manufacturing services, and clinical trials associated with our current product candidates. 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. We plan to increase the total number of our full-time employees from 67 as of May 31, 2009 to approximately 75 to 85 by the end of 2009.

*Revenue*

We have recognized \$3.6 million of revenue from inception through March 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 products 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. If our development efforts for any of our product candidates result in clinical success and regulatory approval or collaboration agreements with third parties, we could generate revenue from those product candidates.

*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

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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.

At any time, we have many ongoing research and development projects.

The following table identifies our current major research and development projects:

<b>Project</b>	<b>Development Status</b>	<b>Expected Near-Term Milestone (1)</b>
OMS103HP Arthroscopic ACL reconstruction	Phase 3	Complete Phase 3 trials and file NDA in second half of 2010
OMS103HP Arthroscopic meniscectomy	Phase 2	Review data from Phase 2 trial in second half of 2009
OMS302 Cataract surgery	Phase 2	Complete Phase 2 trial in mid-2009
OMS201 Ureteroscopy	Phase 1/ Phase 2	Complete Phase 1/ Phase 2 trial in first half of 2010
MASP-2 Macular degeneration, ischemia-reperfusion injury, transplant surgery	Preclinical	Select clinical candidate in second half of 2009
Addiction Addiction and other compulsive behaviors	Preclinical	File IND in second half of 2009
PDE10 Schizophrenia	Preclinical	Select clinical candidate in second half of 2009
PDE7 Parkinson's disease, Restless Legs Syndrome	Preclinical	Select clinical candidate
GPCR Multiple CNS Disorders	Preclinical	Surrogate de-orphanization of orphan GPCR(s)

- (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.



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

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Research and development expenses since inception to March 31, 2009 were \$66.3 million. Our research and development expenses can be divided into research and preclinical development activities and clinical development and regulatory activities. The following table illustrates our expenses associated with these activities:

	<b>Three Months Ended</b>		<b>Years Ended December 31,</b>		
	<b>March 31,</b>	<b>2008</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>2009</b>	<b>2008</b>	<b>(In thousands)</b>		
<b>Clinical Research and Development</b>					
Salaries, benefits, and related costs	\$ 922	\$ 888	\$ 3,521	\$ 2,944	\$ 1,849
Clinical trials	553	688	3,525	3,630	2,116
Manufacturing services, consulting, laboratory supplies, and other costs	332	516	2,080	1,943	825
Other costs	284	241	1,049	633	152
Stock-based compensation	130	186	590	280	181
<b>Total Clinical Research and Development Expenses</b>	<b>2,221</b>	<b>2,519</b>	<b>10,765</b>	<b>9,430</b>	<b>5,123</b>
<b>Preclinical Research and Development</b>					
Salaries, benefits, and related costs	684	650	2,572	2,315	1,848
Research and preclinical studies, consulting, laboratory supplies, and other costs	658	504	2,774	2,566	1,604
Other costs	369	356	1,346	1,412	934
Stock-based compensation	90	141	393	199	128
<b>Total Preclinical Research and Development Expenses</b>	<b>1,801</b>	<b>1,651</b>	<b>7,085</b>	<b>6,492</b>	<b>4,514</b>
<b>Total Research and Development Expenses</b>	<b>\$ 4,022</b>	<b>\$ 4,170</b>	<b>\$ 17,850</b>	<b>\$ 15,922</b>	<b>\$ 9,637</b>
<b>Total Acquired In-process Research and Development Expense</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$ 10,891</b>

Clinical research and development costs consist of clinical trials, manufacturing services, and related personnel costs, and other costs such as rent, utilities and depreciation, and stock-based compensation. Preclinical research and development costs consist of our research activities, preclinical studies, and related personnel costs, laboratory supplies and other costs such as rent, utilities and depreciation, and stock-based compensation. Acquired in-process research and development was recorded in 2006 as an operating expense as a result of our acquisition of the PDE10 program, which we obtained in connection with our purchase of nura, and was determined using the income approach to estimate the present value of future cash flows from the program.

At this time, due to the inherently unpredictable nature of preclinical and clinical development processes and given the early stage of our preclinical product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. While we are currently focused on advancing each of our product development programs, our future research and

development expenses will depend on the clinical success of each product candidate, as well as ongoing assessments of each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

We expect our research and development expenses to increase in the future as we continue the advancement of our clinical trials and preclinical product development programs. 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

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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.

### *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.

### *Investment Income*

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

### *Interest Expense*

Interest expense consists of interest paid on our notes payable.

### *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, 2008, we had federal net operating loss carryforwards and research and development tax credit carryforwards of approximately \$72.5 million and \$2.3 million, respectively. Our net operating loss and research and development tax credit carryforwards will expire between 2009 and 2027 unless utilized prior to such dates. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event 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.



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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.

### *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.

Revenue arrangements are accounted for in accordance with the provisions of Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, and Emerging Issues Task Force, or EITF, No. 00-21, *Revenue Arrangements with Multiple Deliverables*. 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*

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 which varies depending on the site of the clinical trial. 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*

Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, or SFAS 123R, under 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

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expected term, and the fair value of the underlying common stock on the date of grant, among other inputs.

The following table summarizes our assumptions used in the Black-Scholes model:

	<b>Three Months Ended March 31,</b>		<b>Years Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
Expected volatility	71%	60%	60%	60%	60%
Expected term (in years)	6.08	6.08	6.08	6.00-6.08	5.00-6.08
Risk-free interest rate	2.13%	2.80% - 3.40%	2.80% - 3.40%	3.78% - 4.78%	4.57% - 5.04%
Expected dividend yield	0%	0%	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 consists of companies in the biopharmaceutical industry in a stage of development similar to us.

*Expected Term.* We elected to utilize the simplified method for plain vanilla options as provided for in SAB No. 107 and as amended by Staff Accounting Bulletin No. 110, 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 whose term was 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.

SFAS 123R 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. During the fourth quarter of 2008, a revision was made for changes in estimated forfeitures related to stock-based compensation expense, including some immaterial changes that related to prior periods.

*Common Stock Fair Value.* Due to the absence of an active market for our common stock, the fair value of our common stock for purposes of determining the exercise price for stock option grants was determined by our board of directors, with assistance of our management, in good faith based on a number of objective and subjective factors including;

the prices of our convertible preferred stock sold to outside investors in arms-length transactions, and the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock including the liquidation preference of our preferred stock;

our results of operations, financial position, and the status of our research and product development efforts, including continued enrollment in our Phase 3 clinical trials evaluating OMS103HP's safety and ability to improve postoperative joint function and reduce pain following ACL reconstruction surgery, continued enrollment in our clinical trials for OMS302 and OMS201, and advancement of our preclinical development programs;



our stage of development and business strategy;

the composition of and changes to our management team;

the market value of a comparison group of publicly traded pharmaceutical and biotechnology companies that are in a similar stage of development to us;

the lack of liquidity of our common stock as a private company;

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contemporaneous valuations performed by an unrelated valuation specialist prepared in accordance with methodologies not outlined in the *AICPA Practice Aid Valuation of Privately-Held-Company Equity Securities Issued as Compensation*; and

the likelihood of achieving a liquidity event for the shares of our common stock and underlying stock options, such as an initial public offering, or IPO, given prevailing market conditions.

Based on these factors, our board of directors granted options at exercises prices that increased from \$0.50 per share in 2006 up to \$6.33 per share in 2009.

In connection with the preparation of the financial statements necessary for a planned registration of shares with the SEC, in 2007 we reassessed the estimated fair value of our common stock for financial reporting purposes in light of the potential completion of this offering as of December 31, 2006 and at the end of each quarter in 2007 by performing valuation analyses as of each of these dates. In 2008 and 2009, we continued to perform valuation analyses at the end of each quarter. There are significant judgments and estimates inherent in the determination of fair values under SFAS 123R. We used these fair value estimates derived from the valuations to determine the SFAS 123R stock compensation expense recorded in our financial statements.

These valuations were prepared using a methodology that first estimated the fair value of the company as a whole, or enterprise value, and then allocated a portion of the enterprise value to our common stock. This approach is consistent with the methods outlined in the *AICPA Practice Aid Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The valuation methodology utilized in the 2006 reassessment of fair value relied primarily on the market approach to estimate enterprise value giving consideration to the total financing amount received by us, the implied enterprise value of the company based on the convertible preferred stock transactions and market-based industry initial public offering valuations. The income approach was considered as a secondary concurring approach and involved projecting future cash flows and discounting them to present value.

Our enterprise value was allocated to our different classes of equity using the option pricing method. The option pricing method involves making certain other assumptions regarding the anticipated timing of a potential liquidity event, the expected volatility of our equity securities and effects of rights of our convertible preferred stock relative to those of our common stock. The per share price of the Series E convertible preferred stock was higher than the estimated fair value of our common stock as of December 31, 2006, March 31, 2007, and June 30, 2007 since the enterprise valuations used on those dates to estimate the common stock fair value did not rely solely on the Series E preferred financing. Also, the Series E convertible preferred stock pricing reflects rights not attributed to the common stock including: (1) price-based anti-dilution protection, which increases the conversion ratio of our convertible preferred stock if we issue stock at prices lower than the original issue prices of our outstanding convertible preferred stock (subject to certain exceptions); (2) liquidation preferences, which provide that in the event of our acquisition, the holders of our outstanding convertible preferred stock have the right to receive their original investment amounts plus any declared and unpaid dividends prior to the payment of any amounts to the holders of our common stock; (3) dividend rights that require the payment of a dividend on our convertible preferred stock prior to the payment of a dividend on our common stock; (4) the right to elect a majority of our directors; and (5) approval rights with respect to our ability to issue any stock that has rights on parity with or senior to our convertible preferred stock, to pay dividends on our common stock, to redeem any of our outstanding stock (subject to certain exceptions), to sell the company, to increase the number of authorized shares of convertible preferred stock, to amend our articles of incorporation in a manner adverse to the holders of our convertible preferred stock, or to change the authorized number of our directors.



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The valuation methodology utilized in the estimates of fair value from 2007 through 2009 also relied primarily on the market approach to estimate enterprise value and then allocated the enterprise value to our different classes of equity using the probability-weighted expected return, or PWER, method whereby the value of our common stock was estimated based on an analysis of future values for the equity assuming various future outcomes including liquidity events. Our 2007 through 2009 estimated share values are based on the probability-weighted present value of expected investment returns, considering each of the possible future outcomes available to us. In our situation, the future outcomes included three alternatives: (1) we complete an IPO with a pre-money value equal to the highest value of the companies that we surveyed for the valuation analysis, (2) we complete an IPO with a pre-money value equal to the average value of the companies that we surveyed for the valuation analysis, and (3) we have an event in which no liquidity is available for common shareholders. For the first two alternatives, collectively the IPO scenario, the estimated future and present values of our common stock were based on a survey of biotechnology and pharmaceutical companies that completed IPOs in 2006 and 2007, and were calculated using assumptions including: the expected pre-money or sale valuations based on the market approach, the expected dates of the future expected IPO or sale, and an appropriate risk-adjusted discount rate. There were no comparable IPOs completed in 2008 or 2009. For the scenario where we have an event in which no liquidity is available for common shareholders, the estimated value of our common stock was calculated using the cumulative liquidation preferences of the outstanding convertible preferred stock. The present value calculated for our common stock under each scenario was probability-weighted based on our estimate of the probability of each scenario. We assigned weights to each scenario, including the two IPO scenarios, based on significant judgments and estimates that included the impact of operational factors, our estimates regarding when we may be able to complete an IPO and market data.

Finally, the estimated fair value of our common stock was reduced by a discount for lack of marketability. The discount for lack of marketability was analyzed in light of the restrictive factors associated with privately held common stock. For our determination of an appropriate discount for lack of marketability, we used a Longstaff Regression Analysis and a put-option model that considers variables such as time to liquidity, volatility, and the risk-free rate. Based on these analyses and consideration of restrictions, we applied discounts for lack of marketability that declined from 20% in the March 2007 valuation, to 10% in the December 2007 through 2009 valuations, as the then-estimated time to an expected liquidity event decreased.

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*Summary of Stock Option Grants.* Based on the valuations we performed for financial statement purposes, we determined that the stock options we granted in 2009, 2008, 2007 and 2006 had exercise prices different than or equal to the estimated fair values of the common stock at the dates of grant. The following table compares the originally determined fair value and reassessed fair value:

<b>Grant Date</b>	<b>Number of Shares Subject to Options Granted</b>	<b>Exercise Price per Share</b>	<b>Estimated Fair Value of Common Stock per Share at Date of Grant</b>	<b>Intrinsic Value per Share at Date of Grant</b>
July 2006	23,000	\$ 0.50	\$ 0.89	\$ 0.39
September 2006	28,000	0.50	0.89	0.39
December 2006	4,274,853	0.50	0.89	0.39
March 2007	308,500	1.00	1.05	0.05
May 2007	350,000	1.00	3.63	2.63
October 2007	275,733	1.25	6.23	4.98
December 2007	522,500	1.25	6.32	5.07
January 2008	45,000	1.25	6.32	5.07
March 2008	1,200	6.32	6.32	
June 2008	27,000	6.32	6.88	0.56
September 2008	22,000	6.88	6.87	
March 2009	15,500	6.36	6.33	

For purposes of determining stock-based compensation expense, stock options granted in 2006 were valued based on the estimated fair value as of December 31, 2006 and stock options granted in March 2007 and May 2007 were valued based on the estimated fair values determined as of March 31, 2007 and June 30, 2007, respectively. There were no stock options granted during the three months ended September 30, 2007. Stock options granted in October 2007 were valued based on the estimated fair value determined as of September 30, 2007 and stock options granted in December 2007 and January 2008 were valued based on the estimated fair value determined as of December 31, 2007. Stock options granted in March 2008, June 2008, September 2008 and March 2009 were valued based on our latest analysis estimating fair value which were determined as of December 31, 2007, March 31, 2008, June 30, 2008 and December 31, 2008, respectively.

The estimated per share fair value of our common stock from December 31, 2006 to March 31, 2007 increased from \$0.89 to \$1.05. The change in estimated fair value primarily reflects operational factors such as continued advancement in our research and development programs, including additional patient enrollment in our Phase 3 clinical trials evaluating OMS103HP's safety and ability to improve postoperative joint function and reduce pain following ACL reconstruction surgery, or our Phase 3 ACL study. Also, as of March 31, 2007, based on an analysis of the percentage of biotechnology and pharmaceutical companies that had received a round of late-stage venture financing and that had completed an IPO, and because we had made no material progress toward an IPO, we determined that there was a 20% probability of an IPO scenario, divided equally among the two IPO scenarios, and an 80% probability of an event in which no liquidity is available to common shareholders. We ascribed equal weight to each of the two IPO scenarios due to the absence of data supporting one scenario over the other. We also applied a 20% discount for lack of marketability.

The estimated per share fair value of our common stock from March 31, 2007 to June 30, 2007 increased from \$1.05 to \$3.63. The change in estimated fair value reflects the following:

continued advancement in our development programs, including additional patient enrollment in our Phase 3 ACL study and advancement of additional product candidates through preclinical development;

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expanded activities in preparation for an IPO; and

progress towards an IPO.

Because of advancement in our development programs and our progress toward an IPO, we determined that there was a 60% probability of an IPO scenario, divided equally between the two IPO scenarios, and a 40% probability of an event in which no liquidity is available to common shareholders. We also applied a 15% discount for lack of marketability based on a reduction in the amount of time to an expected liquidity event.

The estimated per share fair value of our common stock from June 30, 2007 to September 30, 2007 increased from \$3.63 to \$6.23. The change in estimated fair value reflects the following:

positive efficacy data in a preclinical study evaluating OMS302, our PharmacoSurgery product candidate for use during ophthalmological surgery, and its components in a primate model of lens replacement surgery;

filing of an IND for OMS201, our PharmacoSurgery product candidate being developed for use during urological surgery;

continued advancement in our development programs, including additional patient enrollment in our Phase 3 ACL study; and

continued progress toward an IPO.

Because of advancement in our development programs and our progress toward an IPO, we determined that there was an 85% probability of an IPO scenario (50% probability of an IPO scenario at the high end of the surveyed market data and 35% probability of a scenario at the average of the surveyed market data) and a 15% probability of an event in which no liquidity is available to common shareholders. We attributed more weight to the higher scenario to reflect an increase in the probability of achieving an IPO at the high end of the surveyed market data due to the factors cited above. We applied a 10% discount for lack of marketability based on a reduction in the amount of time to an expected liquidity event.

The estimated per share fair value of our common stock from September 30, 2007 to December 31, 2007 increased from \$6.23 to \$6.32. The change in estimated fair value reflects the following:

initiation of sites for the Phase 2 clinical trial of OMS103HP evaluating the safety and efficacy of the product candidate in patients undergoing meniscectomy surgery;

initiation of sites for the OMS201 Phase 1 clinical trial; and

continued progress toward an IPO together with an extension in the estimated completion date of the IPO compared to our estimate at September 30, 2007.

Because of advancement in our development programs and our additional progress toward an IPO, we determined that there was a 90% probability of an IPO scenario, divided equally among the two IPO scenarios, and a 10% probability of an event in which no liquidity is available to common shareholders. We reduced the probability from the higher market valuation scenario because of the completion of IPOs in the fourth quarter of 2007 at valuations closer to the average valuations than to the higher valuations of the surveyed market data. We applied a 10% discount for lack of marketability based on the expected time to a liquidity event.

The estimated per share fair value of our common stock from December 31, 2007 to March 31, 2008 remained at \$6.32. The estimated fair value reflects the following:

continued advancement in our development programs, including additional patient enrollment in our Phase 3 ACL study and Phase 1 study for OMS201;

advancement of our preclinical development programs;



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filing of an IND for OMS302, our PharmacoSurgery product candidate being developed for use during cataract surgery; and

continued progress toward an IPO together with an extension in the estimated completion date of the IPO compared to our estimate at December 31, 2007.

Because of advancement in our development programs and our progress toward an IPO, we determined that there was a 90% probability of an IPO scenario, divided equally between the two IPO scenarios, and a 10% probability of an event in which no liquidity is available to common shareholders. We also applied a 10% discount for lack of marketability based on the expected time to a liquidity event.

The estimated per share fair value of our common stock from March 31, 2008 to June 30, 2008 increased from \$6.32 to \$6.88. The change in estimated fair value reflects the following:

continued advancement in our development programs, including additional patient enrollment in our Phase 3 ACL study, Phase 1 study for OMS201, and Phase 1/Phase 2 Study for OMS302;

advancement of our preclinical development programs; and

continued progress toward an IPO together with an extension in the estimated completion date of the IPO compared to our estimate at March 31, 2008.

Because of advancement in our development programs and our progress toward an IPO, we determined that there was a 95% probability of an IPO scenario, divided equally between the two IPO scenarios, and a 5% probability of an event in which no liquidity is available to common shareholders. We increased the probability of an IPO to reflect progress in our development programs that could not be reflected in the progress toward an IPO, which is measured by the time to an IPO. We also applied a 10% discount for lack of marketability based on the expected time to a liquidity event.

The estimated per share fair value of our common stock from June 30, 2008 to September 30, 2008 decreased from \$6.88 to \$6.87. The change in estimated fair value reflects the following:

continued advancement in our development programs, including additional patient enrollment in our Phase 3 ACL study and Phase 1/Phase 2 Study for OMS302;

completion of enrollment in our Phase 1 study for OMS201;

advancement of our preclinical development programs;

establishment of debt facility providing up to \$20.0 million in borrowings;

extension of an estimated date for an IPO; and

weakness of the equity capital markets.

We continued to use a 95% probability of an IPO scenario, divided equally among the two IPO scenarios, and a 5% probability of an event in which no liquidity is available to common shareholders. We applied a 10% discount for lack of marketability based on the expected time to a liquidity event.

The estimated per share fair value of our common stock from September 30, 2008 to December 31, 2008 decreased from \$6.87 to \$6.36. The change in estimated fair value reflects the following:

extension of an estimated date for an IPO;

weakness of the equity capital markets;

continued advancement in our development programs, including additional patient enrollment in our Phase 3 ACL study and Phase 1/Phase 2 study for OMS302;

initiation of a Phase 1/Phase 2 study for OMS201;

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advancement of our preclinical development programs; and

draw down of additional \$12.0 million of debt under our debt facility.

We continued to use a 95% probability of an IPO scenario, divided equally among the two IPO scenarios, and a 5% probability of an event in which no liquidity is available to common shareholders. We applied a 10% discount for lack of marketability based on the expected time to a liquidity event.

The estimated per share fair value of our common stock from December 31, 2008 to March 31, 2009 decreased from \$6.36 to \$6.33. The change in estimated fair value reflects the following:

extension of an estimated date for an IPO;

weakness of the equity capital markets;

continued advancement in our development programs, including additional patient enrollment in our Phase 3 ACL study, and completed enrollment in our Phase 1/Phase 2 study for OMS302;

initiation of sites for a Phase 1/Phase 2 study for OMS201; and

advancement of our preclinical development programs.

We continued to use a 95% probability of an IPO scenario, divided equally among the two IPO scenarios, and a 5% probability of an event in which no liquidity is available to common shareholders. We applied a 10% discount for lack of marketability based on the expected time to a liquidity event.

*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, chief medical officer and chairman of the board of directors, we received promissory notes from Dr. Demopulos totaling \$239,000. The promissory notes accrued interest at rates ranging from 3% to 6.25% and were secured by pledges of the underlying common stock. Based on the terms of the notes, the notes were treated as stock options and 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.

*Stock-Based Compensation Summary.* Stock-based compensation expense includes variable awards, amortization of deferred stock compensation, and awards accounted for under SFAS 123R and have been reported in our consolidated statements of operations as follows:

	<b>Three Months Ended</b>		<b>Years Ended December 31,</b>		
	<b>March 31, 2009</b>	<b>2008</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
			<b>(in thousands)</b>		
Research and development	\$ 220	\$ 327	\$ 983	\$ 482	\$ 309

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General and administrative	228	391	1,332	5,574	1,130
Total	\$ 448	\$ 718	\$ 2,315	\$ 6,056	\$ 1,439

At March 31, 2009 there were 989,552 unvested employee options outstanding that will vest over a weighted-average period of 2.5 years. The total estimated compensation expense of these shares is up to \$3.1 million. This excludes non-employee options.

**Table of Contents***Preferred Stock Warrant Liability*

We adopted the provisions of Financial Accounting Standards Board, or FASB, Staff Position 150-5, *Issuer s Accounting under FASB Statement No. 150 for Freestanding Warrants and Other Similar Instruments on Shares That Are Redeemable*, or FSP 150-5, on July 1, 2005. In accordance with FSP 150-5, we estimated the fair value of all outstanding convertible preferred stock warrants at July 1, 2005 and reclassified this amount from equity to a liability. The warrant obligation is adjusted to fair value at the end of each reporting period. Such fair values were estimated using the Black-Scholes option-pricing model and an estimated term equal to each warrant s contractual life. We will continue to adjust the warrant liability for changes in fair value until the earlier of the exercise of the warrants or the completion of a liquidation event, including the completion of this offering, at which time the liability will be reclassified to shareholders equity (deficit).

*Fair Value Measurement of Financial Instruments*

We adopted the provisions of SFAS No. 157, *Fair Value Measurements*, or SFAS 157, effective January 1, 2008, for our financial assets and liabilities. Fair value is defined under SFAS 157 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 provisions of SFAS 157 as it relates to nonfinancial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis. The partial adoption of SFAS 157 did not have a material impact, nor is the full adoption expected to have a material impact, on our financial position, results of operations or cash flows. In October 2008, the FASB issued Staff Position No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*, or FSP 157-3, an interpretation of SFAS 157. We have assessed FSP 157-3 and determined that the guidance is not applicable with respect to our financial assets.

In determining the fair value of our financial assets and liabilities, we used various valuation approaches. SFAS 157 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 reflecting 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 in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and related guidance issued by the FASB and the SEC, in order 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

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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 March 31, 2009, our investment portfolio was made up of cash, cash equivalents, and mortgage-backed, adjustable-rate securities issued by, or fully collateralized by, the U.S. government or U.S. government-sponsored entities. 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. Mortgage-backed securities are priced using round lot non-binding pricing from a single external market source for each of the investment classes within our portfolio. The external sources have historically been primary and secondary broker/dealers that trade and make markets in an open market exchange of these securities. We have used this non-binding pricing information to estimate fair market value and do not make adjustments to these quotes unless a review indicates an adjustment is warranted. To determine pricing, the external market sources use inputs other than quoted prices in active markets that are either directly or indirectly observable such as trading activity that is observable in these securities or similar or like-kind securities, rate reset margins, reset indices, pool diversification and prepayment levels. In addition, in evaluating if this pricing information should be adjusted, the prices obtained from these external market sources are compared against independent pricing services.

We believe that the values assigned to our available-for-sale securities and mortgage backed securities as of March 31, 2009 and December 31, 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 March 31, 2009 and December 31, 2008 and 2007 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**

### *Effect of nura, inc. Acquisition*

Our August 2006 acquisition of nura, inc., or nura, a private biotechnology company, which expanded and diversified our CNS pipeline and strengthened our discovery research capabilities, caused a significant change in our business and results of operations. The acquisition of nura was accounted for as an asset purchase and the results of nura have been included in our results of operations since August 11, 2006. The inclusion of nura for a portion of 2006 impacts the comparability of our 2007 and 2006 financial information with the financial information for previous periods.

We acquired nura through the issuance of 3.4 million shares of Series E convertible preferred stock and 36,246 shares of common stock, and the assumption of a \$2.4 million promissory note, for a total purchase price value of \$14.4 million. The convertible preferred stock issued in conjunction with the acquisition included shares issued to certain nura shareholders in exchange for their \$5.2 million investment in us concurrent with the acquisition. Since nura was a development-stage company, the acquisition was accounted for as an acquisition of assets rather than as a business combination in accordance with EITF 98-3, *Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business*.

We recorded the convertible preferred stock issued to the nura stockholders at its fair value. In valuing the nura acquisition, we followed the guidance as provided in paragraphs 5 and 6 of SFAS 141, which state that the value is measured on the fair value of the consideration given or the fair value of the asset acquired, whichever is more clearly evident,



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and, thus, more reliably measurable. Because the tangible assets of nura were minor in comparison to the intangible assets acquired, we believed that the fair value of the consideration given, our convertible preferred stock, was more clearly evident and measurable.

Of the aggregate purchase price of \$14.4 million, \$3.2 million was allocated to the net tangible assets acquired based on the estimated fair values at the acquisition date, \$310,000 was allocated to intangible assets and \$10.9 million was allocated to in-process research and development as the acquired research projects had not reached technological feasibility and had no alternative use at the acquisition date. We believe that the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions given available facts and circumstances at the acquisition date.

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

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

As a preclinical program, our ability to successfully commercialize a PDE10 product candidate is highly uncertain. It is expected to take a number of years to conduct the necessary preclinical and clinical studies to file for product approval with the FDA and there is no assurance that such studies will be successful. Our development effort for PDE10 is currently supported by funds from The Stanley Medical Research Institute, or SMRI, a non-profit institution that supports research on the causes and treatment of schizophrenia and bipolar disorder. We continue to evaluate our options with respect to our PDE10 program, including partnering with a third-party to offset future development costs.

Selected nura financial information for the period January 1, 2006 to August 11, 2006 is as follows:

	<b>Period from January 1, 2006 to August 11, 2006 (in thousands)</b>
Grant revenue	\$ 200
Research and development expenses	2,394
General and administrative expenses	957
Net loss	3,219

*Comparison of Three Months Ended March 31, 2009 and March 31, 2008*

*Revenue.* Revenue was \$197,000 for the three months ended March 31, 2009 compared with \$234,000 for the three months ended March 31, 2008. The decrease was primarily due to lower grant funding for our PDE10 program, offset by an increase in grant funding related to our PDE7 program.



*Research and Development Expenses.* Research and development expenses were \$4.0 million for the three months ended March 31, 2009 compared with \$4.2 million for the three months ended March 31, 2008. The \$200,000 decrease was due primarily to lower clinical trial expenses as we completed enrollment in our Phase 2 clinical study of OMS103HP for arthroscopic meniscectomy surgery in the first quarter of 2009 and successfully concluded our Phase 1 clinical study for OMS201 during the second half of 2008, as well as lower contract

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services in connection the completion of validation and stability studies for OMS103HP. We expect research and development expenses to increase in the future due to an increased number of product candidates in preclinical studies and clinical trials, as well as the related expansion of our research and development staff.

*General and Administrative Expenses.* General and administrative expenses were \$1.4 million for the three months ended March 31, 2009 compared with \$1.6 million for the three months ended March 31, 2008. The \$200,000 decrease is primarily due to lower stock-based compensation. We expect our general and administrative expenses to increase in the future as we add additional employees and office space to support our anticipated growth as a public company.

*Investment Income.* Investment income was \$81,000 for the three months ended March 31, 2009 compared with \$279,000 for the three months ended March 31, 2008. The decrease is due primarily to a lower average investment balance and lower market rates.

*Interest expense.* Interest expense was \$590,000 for the three months ended March 31, 2009 compared with \$22,000 for the three months ended March 31, 2008. We borrowed a total of \$17.0 million with an annual interest rate of 12.5% under a loan and security agreement with BlueCrest Venture Finance Master Fund Limited, assignee of BlueCrest Capital Finance, L.P., or BlueCrest, in September and December of 2008. Interest expense increased in 2009 due to these borrowings. In 2008, interest expense included interest incurred on a note we assumed in connection with our acquisition of nura in 2006. We paid off the remaining principle amount of \$190,000 due under the assumed note in September 2008.

*Other income (expense).* Other income was \$262,000 for the three months ended March 31, 2009 compared with \$172,000 for the three months ended March 31, 2008. The increase in other income is primarily due to an addition of sublease tenants toward the end of 2008.

*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 our grant from SMRI and approximately \$445,000 less recognized on a government grant in 2008 compared to 2007, as the research related to each grant award was coming to a completion.

*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, additional facility and research costs, and increased preclinical research study costs associated with advancing additional product candidate development, including in 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 non-cash write off of a portion of our deferred offering costs related to this offering from 2007 and 2008 due to delay in the filing of amendment no. 3 to our registration statement on Form S-1, additional personnel, and higher patent legal costs as we continue to broaden our intellectual property portfolio, partially offset by a decrease in audit fees and overall professional services costs in

2008 compared to 2007.

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*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 an increase of \$209,000 from new sublease tenants and \$284,000 less expense from the revaluation of the fair value of warrants in accordance with FAS 150-5 in 2008 compared to 2007.

*Comparison of Years Ended December 31, 2007 and December 31, 2006*

*Revenue.* Revenue was \$1.9 million in 2007 compared with \$200,000 in 2006. Revenue in 2007 and 2006 represents grant funding from third parties related to our MASP-2, PDE10, PDE7 and GPCR programs. The increase was due to research activities related to new grants and advancement of research in these programs during 2007 compared to 2006.

*Research and Development Expenses.* Research and development expenses were \$15.9 million in 2007 compared with \$9.6 million in 2006. The increase was due primarily to additional personnel, which included 13 staff from our acquisition of nura in August 2006, additional facility and research costs subsequent to the nura acquisition, increased clinical trial and manufacturing service costs associated with our Phase 3 clinical trial program for our lead product candidate, OMS103HP, and increased preclinical research study costs associated with advancing additional product candidates, OMS302 and OMS201, toward IND submissions.

*Acquired In-Process Research and Development.* Acquired in-process research and development of \$10.9 million for the year ended December 31, 2006 resulted from our acquisition of nura in August 2006.

*General and Administrative Expenses.* General and administrative expenses were \$10.4 million, including \$5.6 million in stock-based compensation expense, in 2007 compared with \$3.6 million, including \$1.1 million in stock-based compensation expense, in 2006. The \$5.6 million in 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 the period resulted in this expense. Excluding stock-based compensation expense, the increase in general and administrative expenses primarily reflects personnel, consulting, and professional services costs in preparation of an IPO, and higher patent legal costs as we continued to broaden our intellectual property portfolio.

*Investment Income.* Investment income was \$1.6 million in 2007 compared with \$1.1 million in 2006. The increase is due to interest earned on higher cash balances resulting from net proceeds of \$3.2 million and \$34.2 million received from sales of Series E convertible preferred stock in 2007 and 2006, respectively.

*Interest expense.* Interest expense was \$151,000 in 2007 compared with \$91,000 in 2006. We assumed a note payable of \$2.4 million in connection with our acquisition of nura in August 2006. This note bore interest at the lender's prime rate, which was 9.69% at December 31, 2007.

*Other income (expense).* Other (expense) was (\$125,000) in 2007 compared with other income of \$179,000 in 2006. The increase in expense is due to the revaluation of the fair value of warrants in accordance with FAS 150-5 in the amount of \$503,000 offset by sublease income from laboratory space in 2007 compared with 2006.



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**Liquidity and Capital Resources**

Since inception, we have financed our operations primarily through private placements of equity securities and recently through a debt facility. Through March 31, 2009, we received net proceeds of \$77.6 million from the sale of shares of our convertible preferred stock as follows:

in 1994, we issued and sold a total of 875,000 shares of Series A convertible preferred stock for aggregate net proceeds of \$868,000;

in 1998, we issued and sold a total of 2,663,244 shares of Series B convertible preferred stock for aggregate net proceeds of \$4.4 million;

in 2000, we issued and sold a total of 2,825,291 shares of Series C convertible preferred stock for aggregate net proceeds of \$7.2 million;

in 2002, we issued and sold a total of 972,580 shares of Series D convertible preferred stock for aggregate net proceeds of \$3.7 million; and

from 2004 through 2009, we issued and sold a total of 12,895,208 shares of Series E convertible preferred stock for aggregate net proceeds of \$61.2 million.

In September 2008, we entered into a loan and security agreement with BlueCrest to borrow up to \$20.0 million. We have borrowed a total of \$17.0 million under the agreement in three separate tranches.

As of March 31, 2009, we had \$16.8 million in cash, cash equivalents and short-term investments, consisting of \$9.9 million in cash and cash equivalents and \$6.9 million in short-term investments. Our cash, cash equivalents and short-term investment balances are held in a variety of interest-bearing instruments, including 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. The audit report covering our 2008 consolidated financial statements contains an explanatory paragraph stating that our recurring losses and negative cash flows from operations, due to our negative working capital prior to the successful completion of this offering, raise substantial doubt about our ability to continue as a going concern. We believe that the successful completion of this offering will eliminate this doubt and enable us to continue as a going concern; however, if we are unable to raise sufficient capital in this offering, we will need to obtain alternative financing or significantly modify our operational plans for us to continue as a going concern.

Net cash used in operating activities of \$4.7 million for the three months ended March 31, 2009 was primarily due to the net loss for the period of \$5.5 million, offset in part by \$1.1 million of deferred revenue from SMRI grant funding. Net cash used in operating activities of \$19.7 million in 2008 was primarily due to the net loss of \$23.8 million, offset in part by \$2.7 million of non-cash stock-based compensation expense and depreciation and amortization and \$1.5 million from the write-off of deferred offering costs. Net cash used in operating activities of \$14.3 million in 2007 was primarily due to the net loss for the period of \$23.1 million, offset in part by \$6.1 million of non-cash stock-based compensation expense and a \$3.2 million increase in accounts payable and accrued expenses, which was a result of activities from our clinical studies, manufacturing of clinical supplies and costs related to the proposed IPO. Net cash used in operating activities of \$10.2 million in 2006 was primarily a result of the net loss during the period excluding non-cash expenses.

Net cash provided by investing activities was \$415,000 for the three months ended March 31, 2009 primarily due to maturities of investments during the period. Net cash provided by investing activities was \$10.6 million in 2008 primarily due to the sale and maturities of investments in the amount of \$10.7 million. Net cash used in investing activities was \$6.1 million in 2007 and \$579,000 in 2006. Investing activities consist primarily of purchases and sales of marketable securities, and property and equipment purchases.

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Purchases of property and equipment were \$164,000, \$534,000 and \$166,000 in the years ended December 31, 2008, 2007 and 2006, respectively.

Net cash provided by financing activities was \$1.5 million for the three months ended March 31, 2009 primarily due to the sale of 240,000 shares of our convertible preferred stock to SMRI with an estimated fair value of \$1.9 million, offset by \$376,000 in principal payments, which include \$349,000 due on our notes payable to BlueCrest and \$27,000 due on our software financing arrangement. Net cash provided by financing activities was \$15.9 million in 2008 due to borrowing \$17.0 million under the loan with BlueCrest, offset by \$1.0 million of principal payments to pay off the note we assumed in connection with our acquisition of nura. Net cash provided by financing activities was \$2.9 million and \$33.9 million in the years ended December 31, 2007 and 2006, respectively. Net proceeds from these financing activities were primarily related to the sale of our convertible preferred stock.

In September 2008, we entered into a loan and security agreement with BlueCrest to borrow up to \$20.0 million in four tranches. We have borrowed a total of \$17.0 million under the agreement in three separate tranches. Our ability to borrow the fourth tranche of up to \$3.0 million was conditioned on our meeting financing milestones by March 31, 2009 that we did not meet. Interest on borrowings under the loan agreement accrues at an annual rate of 12.5%. Payments under each borrowing tranche are interest only for the first three months and interest and principal thereafter for 36 months. Under the loan agreement, we must satisfy specified conditions prior to any borrowings and comply with affirmative and negative covenants. In addition, if any event, condition or change occurs that has a material adverse effect (as defined in the agreement), BlueCrest may require immediate repayment of all borrowings then currently outstanding. 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 occur prior to September 12, 2018. The success fee amount will be pro rated based on the ratio of the actual amounts borrowed under the loan agreement to the total \$20.0 million that could be borrowed. An exit event is defined in the agreement as including a change in control, a sale of all or substantially all of our assets or an initial public offering of our common stock. If we complete this offering, we will be obligated to pay BlueCrest a success fee of \$340,000.

In connection with the execution of the loan and security agreement, we issued two warrants to BlueCrest to purchase common stock at an exercise price of \$6.88 per share. The warrants vest in tranches, commensurate with our borrowings under the loan agreement. As of March 31, 2009, a total of 49,416 shares of common stock had vested under the first warrant in connection with our drawdowns of the first three tranches available under the loan agreement. The first warrant is fully vested and, because we did not borrow the fourth tranche by March 31, 2009, no shares vested under the second warrant.

In connection with our acquisition of nura in August 2006, we assumed a note payable of \$2.4 million. At December 31, 2007, the note payable balance was \$1.0 million with an interest rate of 9.69%. We paid \$96,000 per month for principal and interest on the note until September 2008 when the remaining principal of \$190,000 due under the note was repaid.





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We have 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 March 31, 2009, we have received \$5.7 million from SMRI, \$3.2 million of which is characterized as grant funding and \$2.5 million of which is characterized as equity funding under the funding agreement.

In November 2008, we entered into an agreement with The Michael J. Fox Foundation, or MJFF, to provide funding for a study of PDE7 inhibitors for the treatment of Parkinson's disease. The agreement is for a one-year period and provides 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 is due in June 2009, conditioned on our compliance with the terms of the agreement, which include our agreement to use the funds solely for the study and to provide progress reports and meet with representatives of MJFF regarding the study.

*Funding Requirements*

We believe that our existing cash, cash equivalents and short-term investments, along with the net proceeds of this offering, will be sufficient to fund our anticipated operating expenses and capital expenditures for at least the next 24 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 associated with our currently anticipated clinical trials.

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 Affitech AS and North Coast Biologics;

- market acceptance of our approved product candidates;

- 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

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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 increases in our 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 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 a later stage of development. 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, 2008.

	<b>Payments Due Within</b>				<b>Total</b>
	<b>1 Year</b>	<b>2-3 Years</b>	<b>4-5 Years</b>	<b>More Than 5 Years</b>	
			<b>(in thousands)</b>		
Operating leases (1)	\$ 1,560	\$ 2,697	\$ 38	\$	\$ 4,295
License maintenance fees	5	10	10	40	65
Notes payable (principal and interest)	3,704	11,759	1,730		17,193
<b>Total</b>	<b>\$ 5,269</b>	<b>\$ 14,466</b>	<b>\$ 1,778</b>	<b>\$ 40</b>	<b>\$ 21,553</b>

(1) We are contracted to receive sublease income of \$603,000 and \$240,000 in 2009 and 2010, 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 March 31, 2009, the maximum amount of royalties

payable to SMRI is \$12.8 million.

If we select a clinical product candidate for our PDE10 program that is a compound synthesized for us by ComGenex, Inc. (subsequently acquired by Albany Medical Research, Inc.), we may be required to pay ComGenex a low single-digit percentage royalty on sales of a PDE10 inhibitor product candidate that includes the compound and make milestones payments of up to \$3.4 million upon the occurrence of certain development events, such as the filing of an IND, the initiation of clinical trials and the receipt of marketing approval.

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If we select a clinical product candidate for our PDE10 program that is a compound synthesized for us by Scottish Biomedical Research, Inc., we may be required to pay Scottish Biomedical a low single-digit percentage royalty on sales of a PDE10 inhibitor product candidate that includes the compound and make milestone payments of up to \$178,000 per selected compound upon the occurrence of certain development events, such as the filing of an IND, the initiation of clinical trials and the receipt of marketing approval.

Pursuant to our MASP-2 antibody discovery and development agreement with Affitech AS, we may be required to pay a low single-digit percentage royalty on any net sales of a product containing a MASP-2 antibody developed by Affitech under the agreement. We also may be required to make additional milestone payments to Affitech of up to \$10.1 million upon the achievement of certain development events related to an Affitech-generated MASP-2 antibody, such as the filing of an IND, initiation of clinical trials and the receipt of marketing approval.

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

Pursuant to our patent assignment agreement with Roberto Ciccocioppo, Ph.D. under which we acquired assets for our Addiction program, we may be required to pay a low single-digit percentage royalty on any net sales of a product from our Addiction program that is covered by any patents that issue from the patent application we acquired from Dr. Ciccocioppo. In addition, if we grant any third parties rights to manufacture, sell or distribute any such products, we must pay to Dr. Ciccocioppo a percentage of any associated fees we receive from such third parties in the range of low single-digits to low double-digits depending on stage of development at which such rights are granted. We also may be required to make milestone payments of up to \$2.3 million upon the achievement of certain development events, such as the initiation of clinical trials and receipt of marketing approval.

## **Related-Party Transactions**

We conduct research using the services of one of our founders, Pamela Pierce Palmer, M.D., Ph.D. Costs incurred for the three months ended March 31, 2009 and the years ended December 31, 2008, 2007, and 2006 totaled \$0, \$5,000, \$5,000 and \$41,000, respectively, and \$445,000 for the period from inception (June 16, 1994) through March 31, 2009. In 2007, we granted Dr. Palmer an option to purchase 40,000 shares of common stock and recognized \$14,000, \$66,000 and \$42,000 of non-cash stock compensation associated with this option for the three months ended March 31, 2009 and the years ended December 31, 2008 and 2007, respectively, and \$122,000 for the period of inception (June 16, 1994) through March 31, 2009.

In conjunction with the exercise of certain stock options by Gregory A. Demopoulos, M.D., our president, chief executive officer, chief medical officer and chairman of the board of directors, we received promissory notes from Dr. Demopoulos totaling \$239,000. The promissory notes accrued interest at rates ranging from 3% to 6.25% and were secured by pledges of the underlying common stock. Based on the terms of the notes, the notes were treated as options subject to variable accounting whereby changes in the estimated fair value of the underlying deemed options were reported as increases or decreases, as applicable, in stock-based compensation expense until such time that the notes were repaid. The notes and accrued interest were repaid in full in December 2007. For the years ended December 31, 2007 and 2006,



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\$5.0 million and \$362,000, respectively, and \$5.6 million for the period of inception (June 16, 1994) through March 31, 2009, has been recognized as stock compensation expense.

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

For a description of additional related-party transactions, see [Certain Relationships and Related-Party Transactions](#).

## **Recent Accounting Pronouncements**

In November 2007, the EITF reached a final consensus on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 requires disclosure of the nature and purpose of our significant collaborative arrangements in the annual financial statements, including our obligations under the arrangement, the amount and income statement classification of significant financial expenditures and commitments, and a description of accounting policies for the arrangement. EITF 07-1 is effective beginning January 1, 2009 and will require us to apply it as a change in accounting principle through retrospective application to all prior periods for all applicable collaborative arrangement existing as of the effective date. There was no impact on our results of operations or financial position upon adoption.

## **Off-Balance Sheet Arrangements**

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

## **Quantitative and Qualitative Disclosures About Market Risk**

Our exposure to market risk is primarily confined to our investment securities and note payable. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality. As of March 31, 2009, we had cash, cash equivalents and short-term investments of \$16.8 million. The securities in our investment portfolio are not leveraged and are classified as available for sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates. While our investment portfolio includes mortgage-backed securities, we do not hold sub-prime mortgages. Our investments in mortgage-backed securities are issued by, or fully collateralized by, the U.S. government or U.S. government-sponsored entities.



**Table of Contents****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 four ongoing PharmacoSurgery clinical development programs, the most advanced of which is in Phase 3 clinical trials. In addition to our PharmacoSurgery platform, we have leveraged our expertise in inflammation and the central nervous system, or CNS, to build a deep and diverse pipeline of preclinical programs targeting large markets. 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 complete the Phase 3 clinical program for ACL reconstruction surgery and, assuming positive results, intend to submit a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, under the Section 505(b)(2) NDA process during the second half of 2010. We believe that OMS103HP will, if approved, be the first commercially available drug product for the improvement of function following arthroscopic surgery. In the second half of 2009, we expect to review the data from our first Phase 2 clinical trial in patients undergoing meniscectomy 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, and we are currently conducting a Phase 2 concentration-ranging clinical trial of the mydriatic agent contained in OMS302 in patients undergoing cataract surgery and a Phase 1/Phase 2 clinical trial of OMS201 in patients undergoing ureteroscopic removal of ureteral or renal stones.

According to market data from SOR Consulting and Thomson Healthcare, approximately a total of: 4.0 million arthroscopic operations, including 2.6 million knee arthroscopy operations; 2.9 million cataract operations; and 4.3 million uroendoscopic operations were performed in the United States in 2006. We expect the number of these operations to grow as the population and demand for minimally invasive procedures increase and endoscopic technologies improve. Based on reports that we commissioned from The Reimbursement Group, or TRG, a reimbursement consulting firm, we anticipate that each of our current PharmacoSurgery product candidates will be favorably reimbursed both to the surgical facility and to the surgeon. As a result, we estimate that there are large markets for each of our PharmacoSurgery product candidates and believe that OMS103HP alone provides a multi-billion dollar market opportunity. We own and exclusively control a U.S. and international portfolio of issued patents and pending patent applications that we believe protects our PharmacoSurgery platform. Our patent portfolio covers all arthroscopic, ophthalmological, urological, cardiovascular and other types of surgical and medical procedures, and includes both method and composition claims



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broadly directed to combinations of agents drawn from distinct classes of therapeutic agents delivered to the procedural site intra-operatively, regardless of whether the agents are generic or proprietary. From this intellectual property estate, we are able to develop a series of proprietary follow-on PharmacoSurgery product candidates.

### *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 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 systemically delivered, such as by oral or intravenous administration, to target these problems 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 Preclinical Development Programs*

In addition to our PharmacoSurgery platform, we have a deep and diverse pipeline of preclinical product development programs targeting large market opportunities in inflammation and the CNS covered by a broad intellectual property portfolio. 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.

Our CNS pipeline includes our Addiction program, our Phosphodiesterase 10, or PDE10, program, our PDE7 program and our G protein-coupled receptors, or GPCR, 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



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addiction to substances of abuse, which may include opioids, nicotine, alcohol and amphetamines, as well as other compulsive behaviors. Based on the previously unknown 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 our PDE10 program, we are developing proprietary compounds to treat schizophrenia. 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. From our proprietary preclinical product candidates we plan to select one or more clinical candidates in the second half of 2009 to advance into toxicology studies in preparation for clinical trials.

Our 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. Based on our promising preclinical animal data in a model of PD showing efficacy of PDE7 inhibitors equivalent to that of levodopamine, we are developing proprietary compounds for the treatment of movement disorders. Levodopamine 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.

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. 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. 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, 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 that we believe can be used in a high-throughput manner to identify synthetic molecules that bind to orphan GPCRs, and we have developed a proprietary platform technology that allows us to create GPCR-specific strains of knock-out mice as well as 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.

We obtained our Addiction program in February 2009 under a patent assignment agreement with Roberto Ciccocioppo, Ph.D. of the Università di Camerino, Italy. We acquired our PDE10, PDE7 and GPCR programs and related patents and other intellectual property rights in 2006 in connection with our \$14.4 million acquisition of nura, inc., or nura, a private biotechnology company, and we hold an exclusive option to purchase the CRA for our GPCR program from Patobios Limited.

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

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

<b>Product Candidate/Program</b>	<b>Targeted Procedure/Disease</b>	<b>Development Status</b>	<b>Expected Near-Term Milestone (1)</b>	<b>Worldwide Rights</b>	
<b><i>Inflammation</i></b>					
OMS103HP	Arthroscopy	Arthroscopic ACL reconstruction	Phase 3	Complete Phase 3 trials and file NDA in second half of 2010	Omeros
OMS103HP	Arthroscopy	Arthroscopic meniscectomy	Phase 2	Review data from Phase 2 trial in second half of 2009	Omeros
OMS302	Ophthalmology	Cataract surgery	Phase 2	Complete Phase 2 trial in mid-2009	Omeros
OMS201	Urology	Ureteroscopy	Phase 1/ Phase 2	Complete Phase 1/ Phase 2 trial in first half of 2010	Omeros
MASP-2		Macular degeneration, ischemia-reperfusion injury, transplant surgery	Preclinical	Select clinical candidate in second half of 2009	In-licensed(2)
<b><i>Central Nervous System</i></b>					
Addiction		Addiction and other compulsive behaviors	Preclinical	File IND in second half of 2009	Omeros
PDE10		Schizophrenia	Preclinical	Select clinical candidate in second half of 2009	Omeros
PDE7		Parkinson's disease, Restless Legs Syndrome	Preclinical	Select clinical candidate	Omeros
GPCR		Multiple CNS Disorders	Preclinical	Surrogate de-orphanization of orphan GPCR(s)	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 PharmacoSurgery product candidates OMS103HP, OMS302 and OMS201.* We are conducting Phase 3 and Phase 2 clinical trials for OMS103HP and we plan to submit an NDA for OMS103HP in the second half of 2010. In addition, we are conducting a Phase 2 clinical trial for OMS302 and a Phase 1/Phase 2 clinical trial for OMS201. Each of these 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 potentially less-costly and time-consuming Section 505(b)(2) NDA process.

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*Maximize commercial opportunity for our PharmacoSurgery product candidates OMS103HP, OMS302 and OMS201.* Our PharmacoSurgery product candidates target large surgical markets with significant unmet medical needs. For each of our product candidates, we have retained all manufacturing, marketing and distribution rights and have not entered into any partnerships granting any of these rights to any third party. Our product candidates do 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. Because accessing the surgeons who perform the procedures targeted by our PharmacoSurgery product candidates requires 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.

*Continue to leverage our business model to mitigate risk by combining our multiple late-stage PharmacoSurgery product candidates with our deep and diverse pipeline of preclinical development programs.* Our lead PharmacoSurgery product is in clinical trials for two distinct therapeutic indications, providing two potential paths for commercialization. We are also advancing two additional PharmacoSurgery product candidates through clinical trials, and from our intellectual property estate we are able to develop a series of proprietary follow-on product candidates. Further, all of these current product candidates consist of generic APIs and are eligible for submission under the potentially less-costly and time-consuming Section 505(b)(2) NDA process. We believe that these attributes collectively mitigate the typical risks of late-stage clinical programs. Leveraging our clinical development experience and our expertise in inflammation and the CNS, we have built multiple development programs, including our PharmacoSurgery and MASP-2 programs targeting large markets focused on inflammation, and our Addiction, PDE10, PDE7 and GPCR programs targeting large markets in disorders of the CNS. By combining our late-stage PharmacoSurgery product candidates with this deep and diverse pipeline of preclinical development programs, we believe that our business model mitigates risk by creating multiple opportunities for commercial success.

*Further expand our broad patent portfolio.* We have made a significant investment in the development of our patent portfolio to protect our technologies and programs, and will continue to do so. We own a total of 21 issued or allowed patents and 52 pending patent applications in the United States, 84 issued or allowed patents and 96 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. Our patent portfolio for our PharmacoSurgery platform is directed to locally delivered compositions and treatment methods using agents selected from broad therapeutic classes such as pain and inflammation inhibitory agents, spasm inhibitory agents, restenosis inhibitory agents, tumor cell adhesion inhibitory agents, mydriatic agents and agents that reduce intraocular pressure. We intend to continue to maintain an aggressive intellectual property strategy in the United States and other commercially significant markets and plan to seek additional patent protection for our existing programs as they advance, for our new inventions and for new products that we develop or acquire.

*Manage our business with continued efficiency and discipline.* We have efficiently utilized our capital and human resources to develop and acquire our product candidates and programs, build a modern research facility and vivarium and create a broad intellectual property portfolio. We operate cross-functionally and are led by an experienced management team with backgrounds in developing and commercializing product candidates. We use rigorous project management techniques to assist us in making disciplined strategic program decisions and to limit the risk profile of our product pipeline.





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In addition, we plan to continue to seek and access external sources of grant funding to support the development of our pipeline programs. We will continue to evaluate opportunities and, as appropriate, acquire technologies that meet our business objectives. We successfully implemented this strategy with our acquisition of nura in 2006, which expanded and diversified our CNS pipeline and strengthened our discovery research capabilities. In addition, we will also consider strategic partnerships to maximize commercial opportunities for our product candidates.

## **Inflammation 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. 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 complete the Phase 3 clinical program for ACL reconstruction surgery and, assuming positive results, intend to submit an NDA to the FDA under the Section 505(b)(2) NDA process during the second half of 2010. In the second half of 2009, we expect to review the data from our first Phase 2 clinical trial in patients undergoing meniscectomy surgery.

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 a complex reaction to tissue injury with multiple pathways, mechanisms and pro-inflammatory mediators, such as PGE<sub>2</sub>, involving three major components:

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

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

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

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

Added to standard irrigation solutions, OMS103HP is delivered directly to the joint throughout arthroscopy, and is designed to act simultaneously at multiple distinct targets to preemptively block the inflammatory cascade induced by arthroscopic surgery. OMS103HP contains the following three active pharmaceutical ingredients, or APIs, each of which are known to interact with different, discrete molecular targets that are involved in the acute inflammatory and pain response:

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

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*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 pro-inflammatory mediators such as substance P and calcitonin gene-related peptide, or CGRP.

In combination, these APIs inhibit PGE<sub>2</sub> production, decrease inflammation-induced vasodilation and prevent increased vascular permeability, as well as block the release of pro-inflammatory 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 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 product for the improvement of 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 to reduce postoperative pain and inflammation such as systemically or intra-articularly delivered NSAIDS, opioids, local anesthetics and steroids. Current pre-operative treatments are not optimally effective because the administration of standard irrigation solution during the surgical procedure washes out pre-operatively delivered drugs. 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



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believe that OMS103HP will provide a number of advantages over current treatments, including:

If approved, OMS103HP will be the first commercially available drug product for the improvement of 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 complete the Phase 3 clinical trials in patients undergoing ACL reconstruction surgery and, assuming positive results, intend to submit an NDA to the FDA under the Section 505(b)(2) process during the second half of 2010.

In our second OMS103HP clinical program, we are conducting a Phase 2 clinical trial to evaluate the safety of OMS103HP in patients undergoing arthroscopic meniscectomy surgery, with exploratory efficacy endpoints focused on the reduction of postoperative pain and improvement in postoperative joint function. Given that there were no serious adverse events considered to be drug-related, enrollment in this trial was discontinued in the first quarter of 2009 to facilitate the design of one or more planned follow-on Phase 3 clinical trials for this program. In the second half of 2009, we expect to review the data from this Phase 2 clinical trial.

By concurrently conducting these two clinical programs for OMS103HP, both evaluating function and pain, with one in patients undergoing arthroscopic ACL reconstruction surgery and the other in patients undergoing arthroscopic meniscectomy surgery, we believe that we are reducing the overall risk profile of the OMS103HP clinical program.

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

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

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

\*p = 0.016, log-rank

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

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

\*p = 0.007, log rank

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



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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.

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

\*p = 0.031, FET

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

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

**Clinical Trial Results – Safety.** 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.

**Intellectual Property Position.** OMS103HP is protected 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. We currently own four issued U.S. Patents, two pending U.S. Patent Applications, and 12 issued patents and nine 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**

**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 dilation, or mydriasis, each

**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.

with well-known safety and pharmacologic profiles. FDA-approved drugs containing each of these APIs have been used in ophthalmological

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clinical practice for more than 15 years, and both APIs are contained in generic, FDA-approved drugs.

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

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

*Market Opportunity.* According to Thomson Healthcare, approximately a total of 2.9 million cataract operations were performed in the United States in 2006. Based on a report that we commissioned from TRG, we believe that OMS302 will be favorably reimbursed both to the surgical facility for its utilization and to the surgeon for its administration and delivery. Also, use of OMS302 does not require a surgeon to change his or her operating procedure. In addition to ease of use, we believe that the clinical benefits of OMS302 could provide surgeons a competitive marketing advantage and may facilitate third-party payor acceptance, all of which we expect will drive adoption and market penetration. We also believe that use of OMS302 will increase the ease of the surgical procedure, thereby increasing patient throughput for both the surgeon and the surgical facility.

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

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

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floppy iris syndrome, this complicates and decreases the safety of cataract surgery, and puts the iris at risk of surgical tear and other damage.

*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 are conducting a Phase 2 concentration-ranging clinical trial in Sweden to assist in determining the optimal concentration of the mydriatic API contained in OMS302 in patients undergoing cataract surgery. This trial, along with our recently completed Phase 1/Phase 2 clinical trial of OMS302, will serve as the basis for additional trials intended to demonstrate the contribution to clinical benefit of each API and establish OMS302 as an effective and safe replacement for currently used ophthalmologic drugs. We expect to complete this Phase 2 clinical trial for OMS302 in mid-2009.

*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-



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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.

*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 5 minutes, and especially 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-mydratic or vehicle control over the first 16 hours immediately following surgery.

*Clinical Trial Results Safety.* OMS302 was well tolerated with no serious adverse events and no discontinuations due to adverse events. The type and number of adverse events were similar across all three treatment groups. Three of the total 61 patients (two in the OMS302 group and one in the OMS302-mydratic group) reported mild to moderate eye pain judged by the investigator to be either possibly or probably treatment-related.

*Intellectual Property.* OMS302 is protected 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, mydratic agents and agents that reduce intraocular pressure, delivered locally and intra-operatively to the site of ophthalmological procedures, including cataract and lens replacement surgery. We currently own two pending U.S. Patent Applications and eight pending patent applications in foreign markets (Australia, Canada, China, Europe, Hong Kong and Japan) that cover OMS302.

*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

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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 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

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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.

*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 the first half of 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.

*Intellectual Property.* OMS201 is protected 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. We currently own three issued U.S. Patents, two pending U.S. Patent Applications, and ten issued patents and 16 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.

**Table of Contents***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 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 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,

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and expect to select a clinical product candidate in the second half of 2009. 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 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, initially in the range of low single-digit to low double-digit and decreasing over time to low single-digit, 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

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adjudged to be insolvent, bankrupt or in receivership and materially limited from performing its obligations under the agreement.

**Central Nervous System Programs**

*Addiction Program*

In our Addiction program, we are developing proprietary compositions that include peroxisome proliferator-activated receptor gamma, or PPAR  $\gamma$ , agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine, alcohol and amphetamines, as well as other compulsive behaviors. Based on the previously unknown link between PPAR  $\gamma$  and addictive disorders together with promising data from European pilot clinical studies and animal models of addiction, we have filed patent applications claiming the use of any PPAR  $\gamma$  agonist, alone or in combination with other agents, for the treatment or prevention of addiction and other compulsive behaviors. According to the National Institutes of Health, the socioeconomic cost of substance abuse in the United States is \$484 billion per year.

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

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

Figure 1 illustrates the effect of treatment with a PPAR  $\gamma$  agonist in a rat model of alcohol addiction. As compared to vehicle control, the administration of a PPAR  $\gamma$  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).

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**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 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.



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*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.

**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.

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**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 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 are currently planning additional studies to evaluate the effects of a PPAR agonist, alone and in combination with other agents, on alcohol, nicotine and opioid addiction. We plan to submit an IND to the FDA in the second half of 2009 to evaluate a PPAR agonist in combination drug product candidates.

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

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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.

*PDE10 Program*

We are developing compounds that inhibit PDE10 for the treatment of schizophrenia. 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. 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. We plan to select one or more clinical candidates in the second half of 2009 to advance into Good Laboratory Practices toxicology studies in preparation for clinical trials. 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 April 30, 2009, we have received \$5.7 million from SMRI, \$3.2 million of which was characterized as grant funding and \$2.5 million of which was characterized as equity funding under the terms of the agreement. 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 March 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.

We previously utilized two contract research organizations to assist us in synthesizing compounds for our PDE10 program, ComGenex, Inc. (subsequently acquired by Albany Medical Research, Inc.) and Scottish Biomedical Research, Inc. If we select a clinical product candidate for our PDE10 program that is a compound synthesized by one of these contract research organizations, we may be required to make milestone payments to that organization upon the occurrence of certain development events, such as the filing of an IND, the initiation of clinical trials and receipt of marketing approval. The total milestone payments potentially



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payable to ComGenex are up to \$3.4 million and to Scottish Biomedical are up to \$178,000 per compound. In such a case, we would also be required to pay to the organization a low single-digit percentage royalty on sales of a PDE10 inhibitor product that includes the organization's compound. We are no longer using either of these contract research organizations to synthesize or develop compounds and the terms of our agreements have ended. We and our other contract research organizations have also synthesized compounds for which we do not have any ongoing or future payment obligations. Due to the inherent uncertainties surrounding preclinical development, at this time we cannot determine whether we will use a compound that Scottish Biomedical or ComGenex synthesized for us, or whether we will use a compound that is not subject to any ongoing or future payment obligations.

**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.

*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 levodopamine, 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.

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**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 MPTP studies evaluating the effects of potential clinical candidates on the development of dyskinesias, a debilitating side effect of current therapies. Should that data be positive, we believe that PDE7 inhibitors could replace L-DOPA and other currently used PD drugs.

The Michael J. Fox Foundation, or MJFF, is providing grant funding for our additional MPTP studies to cover our actual costs incurred, up to a total of \$464,000. In consideration of MJFF's grant funding, we have agreed to provide MJFF limited rights to access the data from our studies. We are not obligated to pay MJFF any royalties or other consideration as a result of the grant funding.

*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 non-sensory 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

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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 227 have known ligands, or non-orphan GPCRs, and 136 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. According to IPR, 125 of the non-orphan GPCRs, or greater than 50% of all 227 non-orphans, are either targeted by marketed drugs or drugs that are in development. Applying that same percentage to the 136 orphan GPCRs, 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 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

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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.

**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, 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



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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 we paid Patobios an additional \$522,000 CAD cash option fee (\$471,000 USD) to extend the option period until December 4, 2009. We have the option to extend this period for one additional six-month option period ending June 4, 2010 by paying Patobios a cash option fee of \$650,000 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. In addition, if during an option period we identify a set of ligands that bind to an orphan GPCR using the assay technology, Patobios will have the option to require us to purchase these assets for the same price we would be required to pay if we elected to purchase them. While we are currently evaluating the utility of these assets for our GPCR program, we are not required to and are not currently attempting to identify any ligands that bind to an orphan GPCR using the assay technology.

### *Acquisition of nura*

We obtained our PDE10, PDE7 and GPCR programs in connection with our August 2006 acquisition of nura, inc., or nura, a private biotechnology company. We acquired all of the equity interests of nura through the issuance of 3.4 million shares of Series E convertible preferred stock and 36,246 shares of common stock to stockholders of nura, and we assumed a \$2.4 million promissory note, for a total purchase value of nura of \$14.4 million. The Series E convertible preferred stock issued in the nura acquisition included \$5.2 million of shares that we sold to certain nura institutional stockholders concurrent with the acquisition. We and the former stockholders of nura have no current continuing or contingent obligations to each other under the agreement pursuant to which we acquired nura.

## **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 free-standing 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.

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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 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. 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 and may require us to conduct additional studies, which we expect would be non-clinical, to demonstrate that liquid OMS103HP is as safe and effective as lyophilized OMS103HP. 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 commitment or, in some cases, terminate the agreement. We are obligated to provide Hospira with the APIs necessary to manufacture OMS103HP as a liquid solution. 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

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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, sufficient quantities of which have been manufactured to support the ongoing Phase 3 clinical program through completion. 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 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 manufacture of all of the clinical supplies 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. Our antibody development agreements with each of these developers require us to pay to the applicable developer a low single-digit percentage royalty on net sales of any product containing an antibody developed for us and milestone payments of up to \$10.1 million and \$4.0 million to Affitech and North Coast, respectively. 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 or if it is determined that further development efforts are futile. 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 in 2009 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. 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. Adoption of our

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PharmacoSurgery product candidates, if approved, may reduce the use of current preoperative and postoperative treatments.

Our preclinical product candidates may face competing products. For example, we are developing PDE10 inhibitors for use in the treatment of schizophrenia. Other pharmaceutical companies, many with significantly greater resources than us, are also developing PDE10 inhibitors for the treatment of schizophrenia and these companies may be further along in development.

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;

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. We own a total of 21 issued or allowed patents and 52 pending patent applications in the United States and 84 issued or allowed patents and 96 pending patent applications in commercially significant foreign markets directed to therapeutic compositions and methods related to our PharmacoSurgery platform and preclinical development programs. We also hold 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. Our patent portfolio includes 14 U.S. and 43 foreign issued or allowed patents, and 11 U.S. and 32 foreign pending patent applications, directed to our PharmacoSurgery product candidates and development programs. Our issued PharmacoSurgery patents have terms that will expire

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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 2029 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, OMS302 and OMS201, respectively, as well as covering the specific combinations of agents included in each of these product candidates.

*OMS103HP Arthroscopy.* OMS103HP is protected 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. We currently own four issued U.S. Patents, two pending U.S. Patent Applications, and 12 issued patents and 9 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 protected 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. We currently own two pending U.S. Patent Applications and eight pending patent applications in foreign markets (Australia, Canada, China, Europe, Hong Kong and Japan) that cover OMS302.

*OMS201 Urology.* OMS201 is protected 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. We currently own three issued U.S. Patents, two pending U.S. Patent Applications, and an additional 10 issued patents and 16 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. We currently

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exclusively control four 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.* We own three pending U.S. Patent Applications and a pending International Patent Cooperation Treaty, or PCT, Patent Application directed to the previously unknown link between PPAR and addictive disorders.

*PDE10 Program.* Medicinal chemistry developments in our PDE10 program have resulted in four pending U.S. and two pending PCT Patent Applications 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.* We own two pending U.S. Patent Applications and a pending international PCT Patent Application directed to the previously unknown link between PDE7 and movement disorders.

*GPCR Program.* We own one issued U.S. Patent, three pending U.S. Patent Applications, one international PCT Patent Application and an additional two issued patents and four pending patent applications in foreign markets (Australia, Canada, Europe and Japan), which are directed to previously unknown links between specific molecular targets in the brain and a series of CNS disorders, and to research tools that are used in our GPCR program.

All of our employees enter into our standard Employee Proprietary Information and Inventions Agreement, which includes confidentiality provisions and provides us ownership of all inventions and other intellectual property made by our employees that pertain to our business or that relate to our employees' work for us or result from the use of our resources. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of the use, formulation and structure of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States, and tests used for determining the patentability of patent claims in all technologies are in flux. The pharmaceutical, biotechnology and other life sciences patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents that we own or have licensed or in third-party patents.

We have retained all manufacturing, marketing and distribution rights for each of our product candidates and programs. Some of our product candidates and programs are based on inventions and other intellectual property rights that we acquired through assignments, exclusive licenses or our acquisition of nura, inc. in August 2006.

*PharmacoSurgery Platform.* Our scientific co-founders, Gregory A. Demopoulos, M.D. and Pamela Pierce Palmer, M.D., Ph.D., conceived the initial invention underlying our PharmacoSurgery platform and transferred all of their related intellectual property rights to us in 1994. Other than their rights as shareholders, our co-founders have not retained any rights to our PharmacoSurgery platform, except that if we file for liquidation under





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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. Demopolos, 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 the University of Leicester license agreement. Under the terms of the University of Leicester and MRC license agreements, we have agreed to pay royalties to each of the University of Leicester and MRC based on a percentage of any proceeds we receive from the licensed technology during the terms of the agreements. We must pay low single-digit 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, initially in the range of low single-digit to low double-digit and decreasing over time to low single-digit, 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 may also sponsor research of MASP-2 by these institutions and 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 a 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.

*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 option to purchase the CRA for our GPCR program from Patobios Limited for approximately \$10.8 million CAD. Our exclusive option with Patobios ends on December 4, 2009, provided that we have the right to extend our option for one additional six-month period ending June 4, 2010 by paying Patobios \$650,000 CAD.

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### **Government Regulation**

Government authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing, and export and import of drug products such as those we are developing. Failure to comply with applicable requirements, both before and after approval, may subject us, our third-party manufacturers, and other partners to administrative and judicial sanctions, such as a delay in approving or refusal to approve pending applications, warning letters, product recalls, product seizures, civil and other monetary penalties, total or partial suspension of production or distribution, injunctions, and/or criminal prosecutions.

In the United States, our products are regulated by the FDA as drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and implementing regulations. Before our drug products may be marketed in the United States, each must be approved by the FDA. Our product candidates are in various stages of testing and none have been approved.

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

preclinical laboratory and animal tests, and formulation studies;

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

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

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

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

FDA review and approval of an NDA.

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

*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



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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.

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

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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 \$17.9 million, \$15.9 million, and \$9.6 million in 2008, 2007, and 2006, respectively.

## **Employees**

As of May 31, 2009, we had 67 full-time employees, 55 of whom are in research and development and 12 of whom are in finance, legal, and administration, including four with M.D.s and 19 with Ph.D.s. None of our employees is represented by a labor union and we consider our employee relations to be good.

## **Facilities**

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.

## **Legal Proceedings**

On September 29, 2008 we filed a complaint, now pending 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 allege 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 seeks 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.



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The following table provides information regarding our current executive officers, key employees and directors:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
<i>Executive Officers:</i>		
Gregory A. Demopulos, M.D.	50	President, Chief Executive Officer, Chief Medical Officer and Chairman of the Board of Directors and, in an interim capacity, Chief Financial Officer and Treasurer
Marcia S. Kelbon, Esq.	49	Vice President, Patent and General Counsel and Secretary
<i>Key Employees:</i>		
George A. Gaitanaris, M.D., Ph.D.	52	Vice President, Science
Wayne R. Gombotz, Ph.D.	50	Vice President, Pharmaceutical Operations
Stephen R. Murray, M.D., Ph.D.	46	Vice President, Clinical Development
J. Greg Perkins, Ph.D.	64	Vice President, Regulatory Affairs and Quality Systems
Clark E. Tedford, Ph.D.	50	Vice President, Research
<i>Directors:</i>		
Ray Aspiri (2)	73	Director
Thomas J. Cable (1)(2)	69	Director
Peter A. Demopulos, M.D., FACC	55	Director
Leroy E. Hood, M.D, Ph.D.	70	Director
Jean-Philippe Triplet (1)	46	Director

(1) Member of our audit committee.

(2) Member of our compensation committee.

(3) Member of our nominating and corporate governance committee.

*Gregory A. Demopulos, M.D.* is one of our founders and has served as our president, chief executive officer, chief medical 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. Prior to founding Omeros, Dr. Demopulos completed his residency in orthopedic surgery at Stanford University and his fellowship training at Duke University. Dr. Demopulos is a named inventor on 19 issued and allowed U.S. patents and 79 issued and allowed foreign patents. 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.

*Marcia S. Kelbon, Esq.* 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.

*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

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biophysical studies and his M.Ph. and M.A. from Columbia University in New York and his M.D. from the Aristotelian University of Greece.

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

*Stephen R. Murray, M.D., Ph.D.* has served as our vice president, clinical development since April 2009. From 2006 to 2009, Dr. Murray served in various positions, most recently as Chief Medical Officer, at Memory Pharmaceuticals, Inc., a biopharmaceutical company that developed treatments for central nervous system disorders, which was acquired by Hoffman-La Roche Inc. in January 2009. From 2005 to 2006, Dr. Murray served at Pfizer Global Pharmaceuticals as a senior medical director and therapeutic team leader for schizophrenia, bipolar disorder and cognition, and from 2004 to 2005 he served as senior medical director and worldwide medical team leader, schizophrenia and as full development team leader, ziprasidone. Prior to 2004, Dr. Murray served as a medical director at Pfizer Pharmaceuticals Group and as an assistant medical director at Janssen Pharmaceuticals. Dr. Murray received his training in psychiatry at the University of California, San Francisco, his M.D. and Ph.D. in molecular and cellular biology from the Medical University of South Carolina and his B.S. from the University of South Carolina.

*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.

*Ray Aspiri* has served on our board of directors since January 1995 and as our treasurer from January 1999 to September 2007. Mr. Aspiri is the chairman of the board of Tempress Technologies, Inc., a research and development company specializing in high-pressure fluid dynamics for the oil and gas industry, which he joined in 1997. From 1980 to 1997, Mr. Aspiri served as the chairman of the board and chief executive officer of Tempress, Inc., a company specializing in products for the truck, marine and sporting goods industries.

*Thomas J. Cable* has served on our board of directors since January 1995. Mr. Cable is the chairman of the board of the Washington Research Foundation, a technology transfer and early stage venture capital organization affiliated with the University of Washington, which he co-founded in 1980. Mr. Cable also founded Cable & Howse Ventures, a venture capital firm, and Cable, Howse & Ragen, an investment banking firm. Mr. Cable also co-founded



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Montgomery Securities, an investment banking firm acquired by Bank of America. A former U.S. Navy submarine officer, Mr. Cable received his M.B.A. from the Stanford Graduate School of Business and his B.A. from Harvard University.

*Peter A. Demopulos, M.D., FACC* has served on our board of directors since January 1995. Dr. Demopulos is a board certified cardiologist and the Medical Director at Seattle Cardiology, a cardiology clinic he joined in 2005. From 1989 to 2005, Dr. Demopulos practiced cardiology at Minor & James Medical PLLC. Dr. Demopulos is also a clinical assistant professor of cardiology at the University of Washington School of Medicine, a position that he has held since 1989, and he participates as an investigator in clinical trials evaluating interventional cardiology devices and drug therapies at Seattle Cardiovascular Research and Swedish Cardiovascular Research. Dr. Demopulos received his M.D. from the Stanford University School of Medicine and his B.S. from Stanford University.

*Leroy E. Hood, M.D., Ph.D.* has served on our board of directors since March 2001. Dr. Hood is the president of the Institute for Systems Biology, a non-profit research institute dedicated to the study and application of systems biology, which he co-founded in 2000. Previously, Dr. Hood was founder and chairman of the Department of Molecular Biotechnology at the University of Washington School of Medicine. Dr. Hood also co-founded Amgen, Inc., Applied Biosystems, Inc., Darwin Molecular Technologies, Inc., Rosetta Inpharmatics, Inc. and SyStemix, Inc. Dr. Hood is a member of the National Academy of Sciences, the American Philosophical Society, the American Association of Arts and Sciences, the Institute of Medicine and the National Academy of Engineering. Dr. Hood received his Ph.D. and B.S. from the California Institute of Technology and his M.D. from The John Hopkins School of Medicine.

*Jean-Philippe Tripet* has served on our board of directors since September 2006. Mr. Tripet served on the board of directors of nura, inc. from September 2003 to August 2006. Mr. Tripet is the chairman and managing partner of Aravis Venture, a venture capital firm that he founded in 2001. Previously, Mr. Tripet served as executive vice president of Lombard Odier & Cie, a commercial bank, where he co-founded and headed the Lombard Odier Immunology Fund, and as vice president equity research of Union Bank of Switzerland. Mr. Tripet received his degree in business administration from the University of Geneva.

## **Board of Directors**

Our business and affairs are organized under the direction of our board of directors, which currently consists of six members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required. Our board of directors has determined that Mr. Aspiri, Mr. Cable, Dr. Hood and Mr. Tripet each meet NASDAQ requirements for independence.

Effective upon the completion of this offering, our articles of incorporation will provide for a classified board of directors consisting of three classes of directors, each serving staggered three-year terms, as follows:

Class I, which will consist of Ray Aspiri and Jean-Philippe Tripet, and whose term will expire at our first annual meeting of shareholders to be held following the completion of this offering;

Class II, which will consist of Thomas J. Cable and Peter A. Demopulos, M.D., and whose term will expire at our second annual meeting of shareholders to be held following the completion of this offering; and

Class III, which will consist of Gregory A. Demopulos, M.D. and Leroy E. Hood, M.D., Ph.D., and whose term will expire at our third annual meeting of shareholders to be held following the completion of this offering.



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At each annual shareholders meeting to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified.

The authorized size of our board is currently nine members. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management.

Peter A. Demopoulos, M.D., FACC and Gregory A. Demopoulos, M.D. are brothers. There are no other family relationships among any of our directors or executive officers.

**Committees of the Board of Directors**

Our board of directors has an audit committee, a compensation committee and a nominating and governance committee, each of which has the composition and responsibilities described below as of the completion of this offering.

*Audit Committee*

The members of our audit committee are Mr. Cable, Mr. Tripet and . Mr. Cable is the chairman of our audit committee. Our board has determined that each member of our audit committee meets current SEC and NASDAQ requirements for independence. Our board of directors has also determined that is an audit committee financial expert as defined in SEC rules. The audit committee is responsible for, among other things:

selecting and hiring our independent auditors, and approving the audit and non-audit services to be performed by our independent registered public accounting firm;

evaluating the qualifications, performance and independence of our independent registered public accounting firm;

monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;

reviewing with our independent registered public accounting firm and management significant issues that arise regarding accounting principles and financial statement presentation, and matters concerning the scope, adequacy and effectiveness of our financial controls;

reviewing the adequacy and effectiveness of our internal control policies and procedures;

establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters;

reviewing and approving in advance any proposed related-party transactions and monitoring compliance with our code of business conduct and ethics; and

preparing the audit committee report that the SEC requires in our annual proxy statement.

*Compensation Committee*

The members of our compensation committee are Ray Aspiri and Thomas J. Cable. Mr. Aspiri is the chairman of our compensation committee. Our board has determined that

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each member of our compensation committee meets current NASDAQ requirements for independence. The compensation committee is responsible for, among other things:

evaluating and recommending to our board of directors the compensation and other terms of employment of our executive officers and reviewing and approving corporate performance goals and objectives relevant to such compensation;

evaluating and recommending to our board of directors the type and amount of compensation to be paid or awarded to board members;

evaluating and recommending to our board of directors the equity incentive plans, compensation plans and similar programs advisable for us;

administering our equity incentive plans;

reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers; and

preparing the compensation committee report that the SEC requires in our annual proxy statement.

*Nominating and Governance Committee*

The members of our nominating and governance committee are , and . Mr. is the chairman of our nominating and governance committee. Our board has determined that each member of our nominating and governance committee meets current NASDAQ requirements for independence. The nominating and governance committee is responsible for, among other things:

assisting the board in identifying prospective director nominees and recommending director nominees to our board for each annual meeting of shareholders;

evaluating nominations by shareholders of candidates for election to our board;

recommending governance principles to our board;

overseeing the evaluation of our board of directors and management;

reviewing shareholder proposals for our annual meetings;

evaluating proposed changes to our charter documents and board committee charters;

reviewing and assessing our senior management succession plan; and

recommending to our board the members for each board committee.

**Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee is an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or



compensation committee.

**Non-Employee Director Compensation**

In the past, we have granted option awards to our non-employee directors in consideration for serving on our board of directors. We have not provided cash compensation to any directors for serving on our board of director or committees of our board of directors. We have reimbursed and will continue to reimburse our non-employee directors for their reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors.

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The following table sets forth summary information concerning the type and total compensation paid or accrued for services rendered to us in all capacities to our non-employee directors for the fiscal year ended December 31, 2008.

**2008 Director Compensation**

Name	Option Awards		Total (\$)
	(\$)(1)	(2)(3)	
Ray Aspiri			
Thomas J. Cable			
Peter A. Demopoulos, M.D.			
Leroy E. Hood, M.D, Ph.D.			
David A. Mann		45,599	45,599
Jean-Philippe Tripet			

- (1) Our directors did not receive any cash compensation during 2008. Amounts shown in this column represent the compensation cost for the year ended December 31, 2008 of option awards granted to each of our non-employee directors as determined in accordance with Statement of Financial Accounting Standards No. 123(revised), or SFAS 123R, using the Black-Scholes option valuation model. The assumptions used to calculate the value of option awards are set forth in Note 11 to our consolidated financial statements included elsewhere in this prospectus. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeiture related to service-based vesting conditions.
- (2) As of December 31, 2008, Mr. Mann held an option award to purchase 25,000 shares of our common stock with an exercise price of \$1.25 per share that vested over a three-year period in equal annual installments. Mr. Mann exercised this option award for 8,333 shares of our common stock in January 2009. Mr. Mann resigned from our board of directors in March 2009.
- (3) As of December 31, 2008, Mr. Aspiri, Mr. Cable and Dr. Hood held option awards to purchase 30,000, 45,000 and 50,000 shares of our common stock, respectively. All of these option awards were fully vested and exercisable as of December 31, 2008.

Following the completion of this offering, all of our directors will be eligible to participate in our 2008 Equity Incentive Plan. For a more detailed description of these plans, see Management Executive Compensation Employee Benefit Plans.

**Executive Compensation***Compensation Discussion and Analysis*

The compensation committee of our board of directors is responsible for establishing and implementing our compensation philosophy and programs for executive officers. The objectives of our executive compensation program are to attract and retain individuals with the skills necessary to help us achieve our business goals, to reward those individuals who help us achieve those goals and to align their interests with those of our shareholders by tying a portion of executive compensation to shareholder value creation. Executive compensation is comprised of the following elements: base salary, annual merit increases, discretionary cash bonuses, stock option awards, severance and change of control benefits, and general benefits that are available to all full-time employees. We do not have any

policies for allocating compensation among the elements of our executive compensation program, nor is the level of one element of compensation substantially dependent on the level of any other element of compensation. However, while we must offer base salaries at competitive rates to attract and retain individuals with the skills necessary to achieve our business goals, we believe that stock option awards are more effective than base salaries at aligning the interests of our executive officers with those of our shareholders. Our goal in setting executive compensation is to motivate our executive officers to achieve our business objectives and, as a result, stock option awards are an important component of an executive's overall compensation.

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In the past, we have determined the level for each element of compensation based on the contributions that each executive officer has made to our success, their respective positions and responsibilities, the experience and knowledge of our management and members of our compensation committee, the relative compensation paid to other members of our senior management, general economic factors and executive compensation surveys (the Radford Global Life Sciences Survey and the Northwest Biotech and Health Technology Salary Survey) that provided summary compensation data of, and public disclosures made by, biotechnology and pharmaceutical companies that we believe are comparable to us based on their location, number of employees, stage of development and resources. Because we have not generally reviewed the compensation of each of our executive officers at the same time, the data we reviewed varied from period to period and from executive to executive. Except for one option award we granted in 2007 to our former chief financial officer, we have not historically established specific individual or corporate performance objectives in setting compensation levels regarding the various components of our compensation package. In the past, our compensation committee has conducted periodic reviews of the compensation of our executive officers. Upon completion of this offering, our compensation committee intends to perform at least annually a review of our executive officers' compensation to determine whether it meets the objectives of our executive compensation program.

The compensation of Gregory A. Demopoulos, M.D., our president, chief executive officer, chief medical officer and chairman of the board of directors, has been determined by our compensation committee. Dr. Demopoulos does not participate in the deliberations of the compensation committee regarding his compensation, although he does participate in negotiations with members of the compensation committee regarding his compensation. The compensation of our other executive officers has been determined by Dr. Demopoulos in consultation with our compensation committee, provided that our compensation committee approves all stock option awards granted to executive officers. We have not engaged third-party consultants with respect to executive compensation matters but expect to do so in the future.

Upon completion of this offering, our compensation committee will determine and review the compensation of our executive officers with the input and advice of our chief executive officer and other members of management; however, an executive officer will not be present during portions of meetings of the compensation committee at which his or her compensation is discussed and approved. In addition, our compensation committee will have the authority to engage third-party consultants to assist it in determining the elements and levels of our executive compensation program, including any individual and corporate performance objectives.

*Base Salary.* We fix the base salaries of our executive officers at levels that we believe enable us to attract and retain individuals with the skills necessary to achieve our business goals and that we believe are competitive with the base salaries paid by comparable pharmaceutical and biotechnology companies.

The annual base salaries of Dr. Demopoulos and Marcia S. Kelbon, our vice president, patent and general counsel are currently \$475,000 and \$285,000, respectively. The annual base salary of Richard J. Klein, our former chief financial officer and treasurer, was \$250,000 when his employment terminated with us in January 2009. We believe that these base salaries are competitive with the base salaries paid by comparable pharmaceutical and biotechnology companies to executive officers with similar positions and experience.

*Discretionary Cash Bonuses.* We have from time to time paid cash bonuses to reward performance achievements, but we have not implemented any plan or policy for awarding cash bonuses to our executive officers. In order to preserve capital, we did not award any cash bonuses to our executive officers in 2008.

*Option Awards.* We grant option awards to our executive officers as a means of aligning their interests with shareholder value creation and to reward long-term performance. In



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determining the size of grants of option awards to executive officers, our compensation committee considers the current equity ownership position of the executive officer, if any, the option awards granted to other senior managers in comparable positions both within our company and at comparable pharmaceutical and biotechnology companies, and the expected impact that the executive officer will have on meeting our business goals and increasing shareholder value. Our option awards to new employees vest over a four-year period beginning on an employee's start date, with 1/4th of the shares vesting on the one-year anniversary of his or her start date and 1/48th of the total shares subject to the option award vesting each month thereafter. In addition to option awards for new employees, we typically grant additional options after an employee has fully vested in all of his or her previously granted option awards that generally vest ratably over 48 months beginning on or near the last vesting date of any previously granted option awards. We have also granted an option award to our former chief financial officer with vesting tied to the achievement of defined business goals.

Because we grant option awards to our executive officers with exercise prices equal to the fair market value of our common stock on the date of grant, our option awards are only valuable to our executive officers if the price of our common stock increases after the date of grant. Our board of directors has historically determined the value of our common stock based on the consideration of several factors applicable to common stock of privately held companies including, among other things, the prices of our convertible preferred stock sold to outside investors, the rights of our convertible preferred stock relative to those of our common stock, our financial position, the status of our research and development efforts, our stage of development and business strategy, the composition of our management team, the market value of similar companies, the lack of liquidity of our common stock and our likelihood of achieving a liquidity event given prevailing market conditions. We do not have any program, plan or obligation that requires us to grant equity compensation on specified dates and, because we have not been a public company, we have not made equity grants in connection with the release or withholding of material non-public information. As a public company, we intend to grant equity awards at the closing public trading price of our common stock on the date of the grant.

To date, a substantial majority of our outstanding option awards have been granted under our Second Amended and Restated 1998 Stock Option Plan, which expired in February 2008, and the nura, inc. 2003 Stock Option Plan. Beginning in March 2008, we only grant option awards under our 2008 Equity Incentive Plan. Please see Management Executive Compensation Employee Benefit Plans for a description of these plans. The 2008 Equity Incentive Plan affords us greater flexibility in granting to our executive officers and other employees a wide variety of equity and equity-related awards, including option awards, stock appreciation rights, restricted stock awards, restricted stock units and performance units and shares. We did not grant any option awards to our executive officers in 2008.

*Severance and Change of Control Benefits.* We have entered into an employment agreement with Dr. Demopulos that provides him severance benefits if we terminate his employment without cause or if he terminates his employment with us for good reason. In addition, pursuant to the terms of our Second Amended and Restated 1998 Stock Option Plan, all option awards granted under that plan to our executive officers will accelerate as to 50% of the unvested shares upon a change of control and 100% of the unvested shares if the acquirer does not assume or replace an executive officer's option awards or if, within one year of the change of control, an executive officer is terminated without cause or constructively terminated. See Management Executive Compensation Potential Payment upon Termination or Change in Control below for a more detailed description and quantification of all of these severance benefits.

We believe that the severance and change of control benefits we provide to Dr. Demopulos are competitive with the benefits offered by comparable pharmaceutical and biotechnology companies to chief executive officers and founders with Dr. Demopulos' tenure, experience

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and performance. In addition, we believe that these benefits help us to retain Dr. Demopulos because they mitigate some of the risks associated with working at a smaller company like ours versus other less risky and better cash remunerated job alternatives that Dr. Demopulos may have. In addition, because of the significant acquisition activity among pharmaceutical and biotechnology companies of our size, the critical role that executive officers play in the successful closing of an acquisition and the risk that an executive officer's employment will be terminated as part of the acquisition, we believe that the change of control benefits that we provide to our executive officers under our Second Amended and Restated 1998 Stock Option Plan are necessary to attract and retain qualified individuals to serve as executive officers and to provide an incentive to contribute to the successful completion of an acquisition.

*General Benefits.* Executive officers are eligible to participate in all of our employee benefit plans, such as medical, dental, vision, life and disability insurance and our 401(k) plan, in each case on the same basis as other employees, subject to applicable law. We also provide vacation and other paid holidays to all employees, including our executive officers, which are comparable to those provided at peer companies.

*Summary Compensation Table*

The following table shows all of the compensation awarded to, earned by, or paid to our principal executive officer, principal financial officer and our other executive officer for the year ended December 31, 2008. The officers listed in the table below are referred to in this prospectus as the named executive officers.

**2008 Summary Compensation Table**

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Option Awards (\$)<sup>(1)</sup></b>	<b>All Other Compensation (\$)</b>	<b>Total (\$)</b>
Gregory A. Demopulos, M.D. President, Chief Executive Officer, Chief Medical Officer and Chairman of the Board of Directors	2008	475,000	594,203	25,225 <sup>(2)</sup>	1,094,428
Marcia S. Kelbon, Esq. Vice President, Patent and General Counsel and Secretary	2008	285,000	67,706	3,049	355,755
Richard J. Klein <sup>(3)</sup> Chief Financial Officer and Treasurer	2008	250,000	202,577	4,092	456,669

(1) Amounts shown do not reflect compensation actually received by the named executive officers. Instead, the dollar amounts shown in this column represent the compensation cost for the year ended December 31, 2008 of option awards granted to each of our named executive officers as determined pursuant to SFAS 123R using the Black-Scholes option valuation model. The assumptions used to calculate the value of option awards are set forth in Note 11 to our consolidated financial statements included elsewhere in this prospectus. Pursuant to SEC rules, the amounts shown exclude the impact of estimated forfeiture related to service-based vesting conditions.

(2) Represents \$25,088 in perquisites and other personal benefits, which included payments for medical malpractice insurance, parking expenses, legal fees, medical practice fees and travel expenses, and \$137 in life insurance premiums.

(3) Mr. Klein's employment with us ended in January 2009.

*Executive Employment Agreements*

*Gregory A. Demopulos, M.D.* We have entered into an employment agreement with Dr. Demopulos dated as of December 30, 2007. Pursuant to the terms of his employment agreement, Dr. Demopulos is an at-will employee and is entitled to receive an annual base salary of \$475,000, which our compensation committee will review at least annually. We may not reduce Dr. Demopulos' annual base salary without his consent, except for a reduction that



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is consistent with an across-the-board reduction in base compensation payable to other employees with the title of director or higher. See Management Executive Compensation Outstanding Equity Awards at Fiscal Year-End below for a description of the outstanding equity awards held by Dr. Demopulos.

Dr. Demopulos is entitled to participate in any bonus and incentive plans or programs that we may establish from time to time for our employees and is eligible to participate in any employee benefit and fringe plans that we make available to our employees with the title of director or higher, such as participation in our 401(k) plan, life insurance and company-paid health insurance. We have also agreed to allow Dr. Demopulos to maintain his status as a board-eligible orthopedic and hand and microvascular surgeon, which includes his performance of surgical procedures on a limited basis, and have agreed to pay related malpractice insurance and professional fees, which were \$18,057 in 2008.

The employment agreement prohibits Dr. Demopulos from competing with us, directly or indirectly, or soliciting our employees to terminate their employment with us or to work with one of our competitors during his employment and for a period of up to two years following termination of his employment. In addition, the employment agreement prohibits him from soliciting or attempting to influence any of our customers or clients to purchase products from our competitors rather than our products.

We have agreed to enter into a new employment agreement with Dr. Demopulos by May 1, 2009. Although we have not yet entered into a new employment agreement with Dr. Demopulos, we and Dr. Demopulos intend to do so. If we are unable to enter into a new agreement with Dr. Demopulos because of our actions or omissions, he could claim that we are in material breach of his current employment agreement, which may entitle Dr. Demopulos to termination benefits. For a description of the termination provisions of Dr. Demopulos' employment agreement, see Management Executive Compensation Potential Payment upon Termination or Change in Control below.

*Marcia S. Kelbon, Esq.* We have not entered into an employment agreement with Ms. Kelbon, and she is an at-will employee. Pursuant to the terms of her employment offer letter, Ms. Kelbon received an initial annual base salary of \$188,300, was granted one option award to purchase 210,000 shares of our common stock with an exercise price of \$0.265 per share and is eligible to participate in our employee benefit plans. This option award vested over a four-year period beginning on October 1, 2001. As of December 31, 2008, Ms. Kelbon's annual base salary was \$285,000. See Management Executive Compensation Outstanding Equity Awards at Fiscal Year-End below for a description of the outstanding equity awards held by Ms. Kelbon.

*Richard J. Klein.* We did not enter into an employment agreement with Mr. Klein, and he was an at-will employee. Pursuant to the terms of his employment offer letter, Mr. Klein received an annual base salary of \$250,000, was eligible to participate in our employee benefit plans and was granted one option award to purchase 250,000 shares of our common stock, or the base award, and another option award to purchase 25,000 shares of our common stock, or the performance award, each with an exercise price of \$1.00 per share. The base award vested over a four-year period beginning May 14, 2007 as follows: 1/4th of the shares subject to the base award vested on May 14, 2008 and 1/48th of the shares subject to the base award vested each month thereafter. The performance award was not eligible to commence vesting unless by May 14, 2008, the one-year anniversary of Mr. Klein's start date, we closed a public or private equity financing (1) in which the number of shares of stock sold in the financing represented no more than 20% of the shares of our stock outstanding, on an as-converted basis, as of the date immediately following the closing of the financing, in each case excluding any shares of stock sold in an initial public offering to underwriters to cover any over-allotments or (2) which met other parameters associated with such financing determined by

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our board of directors. Because we did not meet at least one of those targets by May 14, 2008, the performance award automatically cancelled. In addition, vesting under the base award stopped when Mr. Klein's employment with us ended in January 2009.

Prior to the end of his employment with us, Mr. Klein had the right to exercise these option awards for shares that he was not vested in, provided that if Mr. Klein's employment with us terminated for any reason prior to him vesting into any of shares that he exercised, we have the right, but not the obligation, to repurchase at the original purchase price any shares that Mr. Klein exercised and that he was not vested in as of the date of his termination. As of December 31, 2008, Mr. Klein had exercised a portion of the base award by purchasing 150,000 shares of our common stock at a purchase price of \$150,000. When Mr. Klein's employment with us ended in January 2009, he had vested in 104,166 of the shares subject to the base award, giving us a right to repurchase 45,834 shares that he had exercised but not vested in as of the date of his termination at a cost of \$1.00 per share. Our right to repurchase the unvested shares ends in July 2009. See Management Executive Compensation Outstanding Equity Awards at Fiscal Year-End below for a description of the outstanding equity awards held by Mr. Klein as of December 31, 2008.

*Potential Payments upon Termination or Change in Control*

We have entered into an employment agreement with Dr. Demopoulos that requires us to make payments to him upon termination of his employment in the circumstances described below. In addition, under the terms of our Second Amended and Restated 1998 Stock Option Plan, all of our named executive officers are entitled to acceleration of vesting of their option awards upon our change in control. These arrangements are discussed below.

*Employment Agreement with Gregory A. Demopoulos, M.D.*

The compensation due to Dr. Demopoulos pursuant to his employment agreement in the event of the termination of his employment with us varies depending upon the nature of the termination.

*Termination Without Cause or for Good Reason.* Dr. Demopoulos' employment agreement provides that if we terminate him without cause, as defined below, or if he terminates his employment with us for good reason, as defined below, then until the earlier of (1) two years from the date of his termination and (2) his start date with a new employer that pays him an annual base salary at least equal to the annual base salary we paid to him prior to his termination (provided that if he terminates his employment for good reason because of a reduction in his annual base salary, then the annual base salary that will be measured will be the annual base salary we paid him prior to such reduction), we will be obligated to pay him on our regularly scheduled payroll dates on an annualized basis:

the annual base salary he was receiving as of his termination, provided that if he terminates his employment for good reason because of a reduction in his annual base salary, then the annual base salary we will be obligated to pay him will be his annual base salary in effect prior to such reduction; plus

the greater of (1) the average annual bonus he received in the preceding two calendar years and (2) any bonus he would have been entitled to in the year of his termination as determined by our board of directors in good faith.

In addition, if we terminate Dr. Demopoulos without cause or if he terminates his employment with us for good reason, all of his unvested option awards will immediately vest and become exercisable until the maximum term of the respective option awards and all unvested restricted shares he holds will immediately vest. Dr. Demopoulos and his eligible



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dependents may also continue to participate in all health plans we provide to our employees on the same terms as our employees, unless his new employer provides comparable coverage.

Cause is defined under Dr. Demopulos employment agreement to mean:

his willful misconduct or gross negligence in performance of his duties, including his refusal to comply in any material respect with the legal directives of our board of directors so long as such directives are not inconsistent with his position and duties, and such refusal to comply is not remedied within ten working days after written notice from the board of directors;

dishonest or fraudulent conduct that materially discredits us, a deliberate attempt to do an injury to us, or conduct that materially discredits us or is materially detrimental to the reputation of us, including conviction of a felony; or

his material breach, if incurable, of any element of his confidential information and invention assignment agreement with us, including without limitation, his theft or other misappropriation of our proprietary information.

Dr. Demopulos may terminate his employment for good reason if he terminates his employment with us within 120 days of the occurrence of any of the following events:

any material diminution in his authority, duties or responsibilities;

any material diminution in his base salary;

we relocate his principal work location to a place that is more than 50 miles from our current location; or

we materially breach his employment agreement, which may include, for example, our failure to enter into a new employment agreement by May 1, 2009 because of our actions or omissions.

If any of the above events have occurred as a result of our action, we will have 30 days from notice of such event from Dr. Demopulos to remedy the situation, in which case Dr. Demopulos will not be entitled to terminate his employment for good reason related to the event.

If Dr. Demopulos had been terminated without cause or if he had terminated his employment with good reason on December 31, 2008, Dr. Demopulos would have been entitled to receive an annual base salary of \$475,000 and an annual bonus amount of \$241,889, payable on a bi-monthly basis over a period of up to two years from the date of termination. In addition, option awards with a value of \$ would automatically vest upon his termination, which is the difference between the exercise price of the option awards held by Dr. Demopulos and the assumed initial public offering price of \$ (the mid-point of the range set forth on the cover page of this prospectus), multiplied by the number of shares that would have vested on December 31, 2008 as the result of his termination. Dr. Demopulos and his eligible dependents would also be entitled to participate in the health plans we provide to our employees for a period of up to two years from the date of his termination at a cost to us of approximately \$10,100.

*Termination for Cause, Voluntary Termination, Death or Disability.* If we terminate Dr. Demopulos for cause, if other than for good reason he voluntarily terminates his employment or if his employment is terminated as a result of his death or disability, as defined below, Dr. Demopulos will be entitled to receive payments for all earned but unpaid salary bonuses and vacation time, but he will not be entitled to any severance benefits.

Disability is defined under his employment agreement as his inability to perform his duties as the result of his incapacity due to physical or mental illness, and such inability, which continues for at least 120 consecutive calendar days or 150 calendar days during any

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consecutive twelve-month period, if shorter, after its commencement, is determined to be total and permanent by a physician selected by us and our insurers and acceptable to Dr. Demopulos.

*Second Amended and Restated 1998 Stock Option Plan*

Pursuant to our Second Amended and Restated 1998 Stock Option Plan, or 1998 Stock Plan, in the event of a change in control, as defined below, the vesting of option awards issued pursuant to the 1998 Stock Plan and held by our then-current employees, including those held by Dr. Demopulos and Ms. Kelbon, will be accelerated to the extent of 50% of the remaining unvested shares. If there is no assumption or substitution of outstanding option awards by the successor corporation in the change in control, the option awards will become fully vested and exercisable immediately prior to the change in control. In addition, pursuant to the terms of the 1998 Stock Plan, if within 12 months following a change in control Dr. Demopulos or Ms. Kelbon is terminated without cause or as a result of a constructive termination, as such terms are defined below, any outstanding option awards held by him or her that we issued pursuant to the 1998 Stock Plan will become fully vested and exercisable.

The following terms have the following definitions under the 1998 Stock Plan:

a change in control means proposed sale of all or substantially all of the assets of us, or the merger of us with or into another corporation, or other change in control;

a termination for cause means a termination of an employee for any of the following reasons: (1) his or her willful failure to substantially perform his or her duties and responsibilities to us or a deliberate violation of a company policy; (2) his or her commission of any act of fraud, embezzlement, dishonesty or any other willful misconduct that has caused or is reasonably expected to result in material injury to us; (3) unauthorized use or disclosure by him or her of any proprietary information or trade secrets of ours or any other party to whom he or she owes an obligation of nondisclosure as a result of his or her relationship with us; or (4) his or her willful breach of any of his or her obligations under any written agreement or covenant with us; and

a constructive termination means the occurrence of any of the following events: (1) there is a material adverse change in an employee's position causing such position to be of materially reduced stature or responsibility; (2) a reduction of more than 30% of an employee's base compensation unless in connection with similar decreases of other similarly situated employees; or (3) an employee's refusal to comply with our request to relocate to a facility or location more than 50 miles from our current location; provided that in order for an employee to be constructively terminated, he or she must voluntarily terminate his or her employment within 30 days of the applicable material change or reduction.

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The following table summarizes the benefits that Dr. Demopoulos, Ms. Kelbon and Mr. Klein would have been entitled to receive pursuant to the terms of the 1998 Stock Plan had a change in control occurred on December 31, 2008. The amounts below represent the difference between the exercise price of the option awards issued under the 1998 Stock Plan and held by these employees and the assumed initial public offering price of \$ (the mid-point of the range set forth on the cover page of this prospectus), multiplied by the number of shares that would have vested on December 31, 2008 upon the occurrence of each of the events identified in the table below.

Name	Successor in Change in Control	Successor in Change in Control	Employee is Terminated
	Assumes or Replaces Option Awards (\$)	does not Assume or Replace Option Awards (\$)	Without Cause or Constructively Terminated within Twelve Months of Change in Control (\$)
Gregory A. Demopoulos, M.D.			
Marcia S. Kelbon, Esq.			
Richard J. Klein			

*Employee Benefit Plans**Second Amended and Restated 1998 Stock Option Plan*

Our board of directors adopted our 1998 Stock Plan in February 1998 and our shareholders approved it in February 1998. Our 1998 Stock Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code of 1986, or the Code, to our employees, and for the grant of nonstatutory stock options to our employees, directors and consultants.

*Share Reserve.* We have reserved a total of 8,311,516 shares of our common stock for issuance pursuant to our 1998 Stock Plan. As of March 31, 2009, option awards to purchase 5,311,171 shares of common stock were outstanding, no shares were available for future grant under this plan and 2,391,326 shares had been issued upon the exercise of option awards granted pursuant to this plan. We will not grant any additional option awards under our 1998 Stock Plan. However, the 1998 Stock Plan will continue to govern the terms and conditions of the outstanding awards previously granted thereunder.

*Administration.* Our board of directors or a committee appointed by our board of directors administers our 1998 Stock Plan. Our compensation committee will be responsible for administering all of our equity compensation plans upon the completion of this offering. Under our 1998 Stock Plan, the plan administrator has the power to determine the terms of the awards, including the employees and consultants who will receive awards, the exercise price of each award, the number of shares subject to each award, the vesting schedule and exercisability of each award and the form of consideration payable upon exercise.

*Stock Options.* The exercise price of incentive stock options must be at least equal to the fair market value of our common stock on the date of grant, and their terms may not exceed ten years. The exercise price of nonstatutory stock options may be determined by the plan administrator provided that, if the grantee is our chief executive officer or one of our four most highly compensated executive officers other than our chief executive officer, the per share price may

be no less than 100% of the fair market value. With respect to incentive stock options granted to any participant who owns 10% or more of the voting power of all classes of our outstanding stock as of the grant date, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date.

*Effect of Termination of Service.* Upon termination of a participant's service with us or with a subsidiary of ours, he or she may exercise his or her option award for the period of time stated in the option agreement, to the extent his or her option award is vested on the



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date of termination. In the absence of a stated period in the award agreement, if termination is due to disability, the option award will remain exercisable for up to twelve months following termination or, if termination is due to death or death occurs within 30 days of termination, the option award will remain exercisable for up to 12 months following the date of death. If termination is for cause, the option award will immediately terminate in its entirety. For all other terminations, unless otherwise stated in the award agreement, the option award will remain exercisable for 30 days. An option award may never be exercised after the expiration of its term.

*Effect of a Change of Control.* Our 1998 Stock Plan provides that, in the event of certain change of control transactions, including our merger with or into another corporation or the sale of all or substantially all of our assets, the vesting of the awards will be accelerated to the extent of 50% of the remaining unvested shares. If there is no assumption or substitution of outstanding awards by the successor corporation, the awards will become fully vested and exercisable immediately prior to the change in control unless otherwise determined by the plan administrator at the time of grant. Our 1998 Stock Plan provides that, for certain officers of the company who are terminated without cause or constructively terminated within the twelve months after a change of control transaction, any outstanding award held by them will become fully vested and exercisable.

*Transferability.* Unless otherwise determined by the plan administrator, the 1998 Stock Plan generally does not allow for the sale or transfer of awards under the 1998 Stock Plan other than by will or the laws of descent and distribution, and may be exercised only during the lifetime of the participant and only by that participant.

*Additional Provisions.* Our board of directors has the authority to amend, suspend or terminate the 1998 Stock Plan provided that action does not impair the rights of any participant without the written consent of that participant.

*Plan Amendments and Termination.* Our 1998 Stock Plan automatically terminated in February 2008. However, the 1998 Stock Plan continues to govern the terms and conditions of outstanding awards previously granted thereunder. In addition, our board of directors has the authority to amend the 1998 Stock Plan provided that such action does not impair the rights of any participant.

*nura, inc. 2003 Stock Option Plan*

In connection with our acquisition of nura in August 2006, we assumed the nura, inc. 2003 Stock Option Plan, or 2003 Stock Plan, and all of the option awards issued pursuant to the 2003 Stock Plan that were outstanding as of the date of the acquisition. Our 2003 Stock Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees, and for the grant of nonstatutory stock options to our employees, directors and consultants. The 2003 Stock Plan also allows for the award of stock purchase rights.

*Share Reserve.* A total of 15,192 shares of our common stock are reserved for issuance pursuant to our 2003 Stock Plan. As of March 31, 2009, options to purchase 6,067 shares of common stock were outstanding. We will not grant any additional awards under our 2003 Stock Plan. However, the 2003 Stock Plan will continue to govern the terms and conditions of the outstanding awards previously granted thereunder.

*Administration.* Our board of directors or a committee appointed by our board of directors administers our 2003 Stock Plan. Our compensation committee will be responsible for administering all of our equity compensation plans upon the completion of this offering. Under the nura 2003 Stock Plan, the plan administrator has the power to determine the terms of the awards, including the employees and consultants who will receive awards, the exercise

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price of the award, the number of shares subject to each award, the vesting schedule and exercisability of each award and the form of consideration payable upon exercise.

*Stock Options.* The exercise price of incentive stock options must be at least equal to the fair market value of our common stock on the date of grant, and their terms may not exceed ten years. The exercise price of nonstatutory stock options may be determined by the plan administrator. With respect to incentive stock options granted to any participant who owns 10% or more of the voting power of all classes of our outstanding stock as of the grant date, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date.

*Effect of Termination of Service.* Upon termination of a participant's service with us or with a subsidiary of ours, he or she may exercise his or her option award for the period of time stated in the option agreement, to the extent his or her option award is vested on the date of termination. In the absence of a stated period in the award agreement, if termination is due to death or disability, the option award will remain exercisable for up to twelve months. For all other terminations, unless otherwise stated in the award agreement, the option award will remain exercisable for three months. An option award may never be exercised after the expiration of its term.

*Effect of a Change of Control.* Our 2003 Stock Plan provides that in the event of our merger with or into another corporation or our change in control, the successor corporation will assume or substitute an equivalent award for each outstanding award under the plan. If there is no assumption, substitution or replacement of outstanding awards, such awards will become fully vested and exercisable immediately prior to the merger or change in control, and the administrator will provide notice to the recipient that he or she has the right to exercise such outstanding awards for a period of 15 days from the date of the notice. The awards will terminate upon the expiration of the 15-day period.

*Transferability.* Unless otherwise determined by the plan administrator, the 2003 Stock Plan generally does not allow for the sale or transfer of awards under the 2003 Stock Plan other than by will or the laws of descent and distribution, and may be exercised only during the lifetime of the participant and only by that participant.

*Additional Provisions.* Our board of directors has the authority to amend, suspend or terminate the 2003 Stock Plan without the written consent of a participant, provided that the action does not impair the rights of that participant.

*Plan Amendments and Termination.* Our 2003 Stock Plan will automatically terminate in 2013, unless we terminate it sooner. In addition, our board of directors has the authority to amend, suspend or terminate the 2003 Stock Plan provided such action does not impair the rights of any participant. We will not grant any additional awards under our 2003 Stock Plan and this plan will be terminated upon the completion of this offering but will continue to govern the terms and conditions of outstanding awards previously granted thereunder.

*2008 Equity Incentive Plan*

Our board of directors adopted our 2008 Equity Incentive Plan in February 2008, and our shareholders approved the 2008 Equity Incentive Plan in March 2008. Our 2008 Equity Incentive Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and any parent and subsidiary corporations employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants and our parent and subsidiary corporations employees and consultants.

*Share Reserve.* Upon adoption of the 2008 Equity Incentive Plan, we reserved a total of 1,750,000 shares of our common stock for issuance thereunder plus any shares returned to the



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1998 Stock Plan as a result of termination of options or repurchase of shares issued pursuant to such plan, with the maximum number of shares returned equal to 6,046,303 shares. As of March 31, 2009, 2,187,555 shares of common stock were reserved for issuance pursuant to our 2008 Equity Incentive Plan and options to purchase 65,700 shares of common stock were outstanding.

In addition, our 2008 Equity Incentive Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each fiscal year, beginning with our 2010 fiscal year, equal to the least of:

five percent of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year;

3,500,000 shares; and

such other amount as our board of directors may determine.

*Administration.* Our board of directors or a committee of our board administers our 2008 Equity Incentive Plan. Our compensation committee will be responsible for administering all of our equity compensation plans upon the completion of this offering. In the case of option awards intended to qualify as performance based compensation within the meaning of Section 162(m) of the Code, the committee will consist of two or more outside directors within the meaning of Section 162(m) of the Code. The administrator has the power to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards and the form of consideration payable upon exercise. The administrator also has the authority to institute an exchange program whereby the exercise prices of outstanding awards may be reduced, outstanding awards may be surrendered in exchange for awards with a higher or lower exercise price and/or cash, or outstanding awards may be transferred to a third party.

*Option Awards.* The exercise price of option awards granted under our 2008 Equity Incentive Plan must generally at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed ten years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock as of the grant date, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. In addition, the term of an option granted to a resident of California prior to the effective date of the registration statement to which this prospectus is a part may not exceed ten years. The administrator determines the term of all other option awards.

After termination of an employee, director or consultant, he or she may exercise his or her option award for the period of time stated in the option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for twelve months. In all other cases, the option will generally remain exercisable for three months. However, an option may not be exercised later than the expiration of its term.

*Stock Appreciation Rights.* Stock appreciation rights may be granted under our 2008 Equity Incentive Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. The administrator determines the terms of stock appreciation rights, including when such rights become exercisable and whether to pay the increased appreciation in cash or with shares of our common stock, or a combination thereof. Stock appreciation rights expire under the same rules that apply to stock options.

*Restricted Stock Awards.* Restricted stock may be granted under our 2008 Equity Incentive Plan. Restricted stock awards are shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee. The

administrator

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may impose whatever conditions to vesting it determines to be appropriate. For example, the administrator may set restrictions based on the achievement of specific performance goals. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

*Restricted Stock Units.* Restricted stock units may be granted under our 2008 Equity Incentive Plan. Restricted stock units are awards of restricted stock, performance shares or performance units that are paid out in installments or on a deferred basis. The administrator determines the terms and conditions of restricted stock units including the vesting criteria and the form and timing of payment.

*Performance Units and Shares.* Performance units and performance shares may be granted under our 2008 Equity Incentive Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals in its discretion, which, depending on the extent to which they are met, will determine the number and/or the value of performance units and performance shares to be paid out to participants. Performance units shall have an initial dollar value established by the administrator prior to the grant date. Performance shares will have an initial value equal to the fair market value of our common stock on the grant date. Payment for performance units and performance shares may be made in cash or in shares of our common stock with equivalent value, or in some combination, as determined by the administrator.

*Transferability of Awards.* Unless the administrator provides otherwise, our 2008 Equity Incentive Plan does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

*Change in Control Transactions.* Our 2008 Equity Incentive Plan provides that in the event of our change in control, the successor corporation or its parent or subsidiary will assume or substitute an equivalent award for each outstanding award or replace each outstanding award with a comparable cash incentive program of the successor corporation or its parent or subsidiary based on the award value at the time of the transaction. If awards are assumed, substituted or replaced as described above, options and stock appreciation rights will vest as to 50% of their unvested shares, restriction on restricted stock and restricted stock units will lapse with respect to 50% of shares subject to such restrictions and with respect to performance-based awards, all performance goals or other vesting criteria will be deemed achieved at 100% of the target levels and all other terms and conditions will be deemed met with respect to 50% of the shares subject to such terms and conditions. If there is no assumption or substitution of outstanding awards and no replacement of outstanding awards with such cash incentive program, the awards will fully vest, all restrictions will lapse and become fully exercisable. The administrator will provide notice to the recipient that he or she has the right to exercise the option and stock appreciation right as to all of the shares subject to the award, all restrictions on restricted stock will lapse, and all performance goals or other vesting requirements for performance shares and units will be deemed achieved, and all other terms and conditions met. The option or stock appreciation right will terminate upon the expiration of the period of time the administrator provides in the notice. In the event the service of an outside director is terminated on or following a change in control, other than pursuant to a voluntary resignation, his or her options and stock appreciation rights will fully vest and become immediately exercisable, all restrictions on restricted stock will lapse, and all performance goals or other vesting requirements for performance shares and units will be deemed achieved, and all other terms and conditions met.

*Plan Amendments and Termination.* Our 2008 Equity Incentive Plan will automatically terminate in 2018, unless we terminate it sooner. In addition, our board of directors has the authority to amend, suspend or terminate the 2008 Equity Incentive Plan provided such action does not impair the rights of any participant.

**Table of Contents***Individual Option Awards*

On December 11, 2001 we granted individual option awards to purchase an aggregate of 148,906 shares of our common stock to two of our founders, including Gregory A. Demopoulos, M.D., our president, chief executive officer, chief medical officer and chairman of the board of directors. These option awards were fully vested upon grant and are exercisable until December 11, 2011. As of March 31, 2009, option awards to purchase an aggregate of 58,806 shares of our common stock, with an exercise price of \$0.265 per share, were outstanding under these individual option awards.

*401(k) Plan*

We maintain a 401(k) Plan that is intended to be a tax-qualified retirement plan. The 401(k) Plan covers all of our employees who meet eligibility requirements. Currently, employees may elect to defer up to 75% of their compensation, or the statutorily prescribed limit, if less, to the 401(k) Plan. Under the 401(k) Plan, we may elect to make a discretionary contribution or match a discretionary percentage of employee contributions but we currently do not make any contributions nor have we matched any employee contributions. The 401(k) Plan has a discretionary profit sharing component, which to date we have not implemented, whereby we can make a contribution in an amount to be determined annually by our board of directors. An employee's interests in his or her deferrals are 100% vested when contributed. The 401(k) Plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As such, contributions to the 401(k) Plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) Plan, and all contributions are deductible by us when made.

*Outstanding Equity Awards at Fiscal Year-End Table*

The following table shows certain information regarding outstanding equity awards held by each of the named executive officers as of December 31, 2008.

**2008 Outstanding Equity Awards at Fiscal Year-End**

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Option Awards Number of Securities Underlying		Option Exercise Price (\$)	Option Expiration Date	Stock Awards	
		Unexercised Options (#)	Option Exercise Price (\$)			Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(2)
Gregory A. Demopoulos, M.D.	3,025			0.265	12/10/11		
	766,666	33,334(3)		0.50	12/11/16		
	1,150,000	50,000(3)		0.50	12/11/16		
	50,000	150,000(4)		1.25	12/29/17		

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Marcia S. Kelbon, Esq.	300,833	79,167(5)	0.50	12/11/16	
	2,500	7,500(4)	1.25	12/29/17	
Richard J. Klein	100,000(6)		1.00	05/13/17	51,042(6)
	2,500	7,500(4)	1.25	12/29/17	

- (1) These option awards were granted pursuant to the 1998 Stock Plan, which provides for the automatic vesting of at least a portion of any unvested options upon a change of control transaction as described under the section of this prospectus entitled Management Employee Benefit Plans Second Amended and Restated 1998 Stock Option Plan.
- (2) The market value of shares of stock that have not vested has been calculated using the assumed initial public offering price of \$ per share (the mid-point of the range set forth on the cover page of this prospectus).
- (3) The shares subject to the option award vest on a monthly basis in equal amounts over a four-year period that began on February 28, 2005.
- (4) 1/4th of the shares subject to the option award vest on December 30, 2008 and 1/48th of the shares subject to the option award vest each month thereafter.



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- (5) The shares subject to the option award vest on a monthly basis in equal amounts over a four-year period that began on October 1, 2005.
- (6) A total of 250,000 shares were subject to this option award. 1/4th of the shares subject to the option vested on May 14, 2008 and 1/48th of the shares vested each month thereafter. Pursuant to the terms of the option award, Mr. Klein had the right to purchase unvested shares, provided that if his employment terminated for any reason prior to him vesting into any shares that he exercised, we have the right, but not the obligation, to repurchase at the original purchase price any shares that he exercised and is not vested in as of the date of his termination. As of December 31, 2008, Mr. Klein had purchased 150,000 of these shares, 98,958 of which were vested. Mr. Klein's employment with us ended in January 2009, at which time 104,166 of these shares were vested. Our right to repurchase the unvested shares ends in July 2009.

*Option Exercises and Stock Vested Table*

The following table shows certain information regarding option exercises by each of the named executive officers during the year ended December 31, 2008.

**2008 Option Exercises and Stock Vested**

<b>Name</b>	<b>Stock Vested</b>	
	<b>Number of Shares Acquired on Vesting (#)</b>	<b>Value Realized on Vesting (#)(1)</b>
Gregory A. Demopoulos, M.D.		
Marcia S. Kelbon, Esq.		
Richard J. Klein	98,958	

- (1) The value realized on vesting has been calculated using the assumed initial public offering price of \$      per share (the mid-point of the range set forth on the cover page of this prospectus).

*Pension Benefits*

None of our named executive officers participates in or has account balances in qualified or non-qualified benefit plans sponsored by us.

*Nonqualified Deferred Compensation*

None of our named executive officers participates in or has account balances in nonqualified defined contribution plans or other deferred compensation plans maintained by us.

*Limitation of Liability and Indemnification*

Our articles of incorporation contain provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Washington law. Consequently, our directors will not be personally liable to us or our

shareholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

acts or omissions that involve intentional misconduct or a knowing violation of law;

unlawful distributions; or

any transaction from which the director will personally receive a benefit in money, property or services to which the director is not legally entitled.

Our articles of incorporation and our bylaws provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Washington law. Any repeal of or modification to our articles of incorporation or bylaws may not adversely affect any right or protection of a director or officer for or with respect to any acts or omissions of such director or officer occurring prior to such amendment or repeal. Our bylaws will also provide that we shall advance expenses incurred by a director or officer in advance of the final

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disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Washington law.

We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these charter provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions contained in our articles of incorporation and bylaws may discourage shareholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other shareholders. Further, a shareholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

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**CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS**

The following is a summary of transactions since January 1, 2006 to which we have been a party in which the amount involved exceeded \$120,000 and in which any of our executive officers, directors or beneficial holders of more than five percent of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus entitled Management Non-Employee Director Compensation and Management Executive Compensation.

**Stock Issuances**

*Option Award Exercises*

Since January 1, 2006, Gregory A. Demopoulos, M.D., our president, chief executive officer, chief medical officer and chairman of the board of directors and holder of more than five percent of our capital stock, has purchased 20,000 and 259,917 shares of our common stock at prices of \$0.175 and \$0.2915 per share, respectively, by exercising option awards granted pursuant to our 1998 Stock Plan, resulting in an aggregate purchase price of \$79,266.

Since January 1, 2006, Marcia S. Kelbon, our vice president, patent and general counsel and secretary, has purchased 147,500 shares of our common stock at a price of \$0.265 per share by exercising an option award granted pursuant to our 1998 Stock Plan, resulting in an aggregate purchase price of \$39,088.

In June 2007, Richard J. Klein, our former chief financial officer and treasurer, purchased 150,000 shares of our common stock at a price of \$1.00 per share by exercising an option award granted pursuant to our 1998 Stock Plan, resulting in an aggregate purchase price of \$150,000. Pursuant to the terms of his option award, Mr. Klein had the right to exercise his option award for shares that he was not vested in. In January 2009 when his employment with us ended, Mr. Klein had vested in 104,166 of the 150,000 shares of common stock that he purchased by exercising his option award. Because Mr. Klein's employment ended before he fully vested in the shares that he purchased, we have the right, but not the obligation, to repurchase the 45,834 unvested shares at a price of \$1.00 per share. Our right to repurchase the unvested shares initially ended in April 2009; however, on April 29, 2009, prior to the expiration of the repurchase period, we entered into an agreement with Mr. Klein to extend the repurchase period to July 28, 2009.

*Common Stock Warrant Exercises*

In December 2007, Thomas J. Cable, Gregory A. Demopoulos, M.D., Peter A. Demopoulos, M.D., FACC and Aspiri Enterprises, LLC, of which Ray Aspiri is the managing partner and a member, each purchased 17,857 shares of our common stock at a price of \$1.75 per share by exercising common stock warrants granted to them in December 1997 in connection with their agreements to guarantee a loan made to us by a third party that we have repaid.

*Acquisition of nura, inc.*

On August 11, 2006, we issued to the related persons named in the table below the following number of shares of our Series E convertible preferred stock and common stock in connection with our acquisition of nura, inc.

Name	Series E Convertible Preferred Stock (#)	Common Stock (#)
------	--	---------------------

Aravis Venture I, L.P.(1)	559,551	6,925
Entities affiliated with ARCH Venture Partners (2)	839,326	7,741

- (1) Jean-Philippe Tripet, a member of our board of directors, is managing partner of Aravis Venture I, L.P. Mr. Tripet holds the title of Director of Aravis General Partner Ltd., which serves as general partner of Aravis Venture I, L.P.

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Mr. Tripet disclaims beneficial ownership of the shares held by Aravis Venture I, L.P., except to the extent of his proportionate pecuniary interest therein.

- (2) Represents (a) 833,787 and 7,690 shares of Series E convertible preferred stock and common stock, respectively, held by ARCH Venture Fund V, L.P. and (b) 5,539 and 51 shares of Series E convertible preferred stock and common stock, respectively, held by ARCH V Entrepreneurs Fund, L.P. These two associated partnerships together hold more than five percent of our capital stock.

*Private Placement of Series E Convertible Preferred Stock*

On August 21, 2006, we issued and sold to the related persons named in the table below the following number of shares of our Series E convertible preferred stock at a price of \$5.00 per share.

Name	Series E Convertible Preferred Stock (#)	Aggregate Purchase Price (\$)
Aravis Venture I, L.P.	400,000	2,000,000
Entities affiliated with ARCH Venture Partners (1)	600,000	3,000,000

- (1) Represents 595,984 and 4,016 shares of Series E convertible preferred stock that we issued and sold to ARCH Venture Fund V, L.P. and ARCH V Entrepreneurs Fund, L.P., respectively.

*Agreement and Plan of Reorganization with nura, inc.*

In connection with our acquisition of nura on August 11, 2006, we entered into an agreement and plan of reorganization with nura that provides for the issuance of our capital stock in exchange for all of the outstanding capital stock of nura. In connection with this agreement, 15% of the shares of Series E convertible preferred stock that we issued to the former holders of nura capital stock were placed into escrow until February 11, 2008 to secure claims we may bring for indemnification pursuant to the agreement, including 83,932, 125,068 and 830 shares issued to Aravis Venture I, L.P., ARCH Venture Fund V, L.P. and ARCH V Entrepreneurs Fund, L.P., respectively. These shares of Series E convertible preferred stock were released from escrow in February 2008 and will automatically convert into an equivalent number of shares of common stock upon the completion of this offering. In addition, ARCH Venture Corporation, which is affiliated with ARCH Venture Partners, was named as the agent of the former stockholders of nura, inc. under the agreement and plan of reorganization.

**Amended and Restated Investors Rights Agreement**

We have entered into an amended and restated investors rights agreement with the purchasers of our convertible preferred stock and certain holders of our common stock, including entities affiliated with ARCH Venture Partners, Aravis Venture I, L.P., Aspiri Enterprises, LLC, Thomas J. Cable, Gregory A. Demopulos, M.D., Peter A. Demopulos, M.D., FACC and Leroy E. Hood, M.D., Ph.D. The holders of 26,527,802 shares of our common stock, including the shares of common stock issuable upon conversion of all outstanding shares of our convertible preferred stock, are entitled to registration rights with respect to these shares under the Securities Act of 1933, as amended. For a more detailed description of these registration rights, including the limitations on these rights related to this offering, see Description of Capital Stock Registration Rights.

**Loans**

On December 31, 2002, March 13, 2003, December 31, 2003 and December 31, 2005 we made loans to Gregory A. Demopulos, M.D. with principal amounts of \$65,000, \$28,116, \$58,300 and \$87,450, respectively, that accrue interest on the principal amounts at annual rates of 4.5%, 4.5%, 3.0% and 6.25%, respectively. Dr. Demopulos used the proceeds from these loans to exercise option awards that had terms of five years. Each of these loans was secured by our common stock held by Dr. Demopulos. In December 2007, the full balance of \$278,011, including \$238,866 of principal and \$39,145 accrued interest, was repaid.

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**Technology Transfer Agreements**

In June 1994, we entered into a technology transfer agreement with Gregory A. Demopoulos, M.D. pursuant to which he irrevocably transferred to us all of his intellectual property rights in our PharmacoSurgery platform. In December 2001, we entered into a second technology transfer agreement with Dr. Demopoulos pursuant to which he irrevocably transferred to us all of his intellectual property rights in our Chondroprotective program. Other than his rights as a shareholder, Dr. Demopoulos has not retained any rights to our PharmacoSurgery platform or Chondroprotective program, 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, Dr. Demopoulos and another one of our co-founders, Pamela Pierce Palmer, M.D., Ph.D., have the right to repurchase the initial PharmacoSurgery intellectual property at the then-current fair market value.

**Policies and Procedures for Related-Party Transactions**

We intend to adopt a formal policy that our executive officers, directors, and principal shareholders, including their immediate family members, are not permitted to enter into a related-party transaction with us without the approval of our audit committee. Any request for us to enter into a transaction with an executive officer, director, principal shareholder, or any of such persons' immediate family members, in which the amount involved exceeds \$120,000, other than transactions involving compensation for services provided to us as an executive officer or director, must be presented to our audit committee for review, consideration and approval. All of our directors and executive officers are required to report to our audit committee any such related-party transaction. In approving or rejecting the proposed related-party transaction, our audit committee shall consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, whether the transaction is fair to us and whether the terms of the transaction would be similar if the transaction did not involve a related party, whether the transaction would impair the independence of a non-employee director, the materiality of the transaction and whether the transaction would present an improper conflict of interest between us and the related party. This policy will become effective upon completion of this offering and is intended to meet NASDAQ listing requirements. All of the transactions described above were entered into prior to the adoption of this policy.



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The following table sets forth certain information with respect to the beneficial ownership of our common stock at March 31, 2009, as adjusted to reflect the sale of common stock offered by us in this offering, for:

each person who we know beneficially owns more than five percent of our common stock;

each of our directors;

each of our named executive officers; and

all of our directors and executive officers as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 28,355,306 shares of common stock outstanding at March 31, 2009. For purposes of the table below, we have assumed that \_\_\_\_\_ shares of common stock will be outstanding upon completion of this offering. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options, warrants or other convertible securities held by that person that are currently exercisable or exercisable within 60 days of March 31, 2009. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Omeros Corporation, 1420 Fifth Avenue, Suite 2600, Seattle, Washington 98101.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
<b>5% Shareholders:</b>			
Entities affiliated with ARCH Venture Partners (1)	1,447,067	5.1%	
<b>Directors and Executive Officers:</b>			
Gregory A. Demopoulos, M.D. (2)	4,965,396	16.3%	
Marcia S. Kelbon, Esq. (3)	553,957	1.9%	
Richard J. Klein (4)	152,916	*	
Ray Aspiri (5)	317,857	1.1%	
Thomas J. Cable (6)	194,163	*	
Peter A. Demopoulos, M.D., FACC (7)	517,045	1.8%	
Leroy E. Hood, M.D., Ph.D. (8)	106,603	*	
Jean-Philippe Tripet (9)	966,476	3.4%	

All executive officers and directors as a group (8 persons) (10)	7,774,413	25.2%
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\* Less than one percent

(1) Represents (a) 1,437,461 shares of common stock held by ARCH Venture Fund V, L.P., or ARCH V, and (b) 9,606 shares of common stock held by ARCH V Entrepreneurs Fund, L.P., or the Entrepreneurs Fund. ARCH Venture Partners V, L.P., or the GPLP, as the sole general partner of ARCH V and the Entrepreneurs Fund, has

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the power to vote and dispose of the shares held of record by ARCH V and the Entrepreneurs Fund and may be deemed to beneficially own certain of the shares held of record by ARCH V and the Entrepreneurs Fund. The GPLP disclaims beneficial ownership of all shares held of record by ARCH V and the Entrepreneurs Fund in which the GPLP does not have an actual pecuniary interest. ARCH Venture Partners V, LLC, or the GPLLC, as the sole general partner of the GPLP, has the power to vote and dispose of the shares held of record by ARCH V and the Entrepreneurs Fund and may be deemed to beneficially own certain of the shares held of record by ARCH V and the Entrepreneurs Fund. The GPLLC disclaims beneficial ownership of all shares held of record by ARCH V and the Entrepreneurs Fund in which it does not have an actual pecuniary interest. Keith Crandell, Steven Lazarus, Clinton Bybee and Robert Nelsen are the managing directors of the GPLLC, share the power to vote and dispose of the shares held of record by ARCH V and the Entrepreneurs Fund and may be deemed to beneficially own certain of the shares held of record by ARCH V and the Entrepreneurs Fund. The managing directors disclaim beneficial ownership of all shares held of record by ARCH V and the Entrepreneurs Fund in which they do not have an actual pecuniary interest. The address of all filing persons is 8725 W. Higgins Road, Suite 290, Chicago, IL 60631.

- (2) Includes 2,073,858 shares of common stock that Dr. Demopoulos has the right to acquire from us within 60 days of March 31, 2009 pursuant to the exercise of option awards.
- (3) Includes 343,957 shares of common stock that Ms. Kelbon has the right to acquire from us within 60 days of March 31, 2009 pursuant to the exercise of option awards.
- (4) Represents (a) 150,000 shares of common stock that Mr. Klein acquired from us pursuant to the exercise of an option award and (b) 2,916 shares of common stock that Mr. Klein had the right to acquire from us within 60 days of March 31, 2009 pursuant to the exercise of option awards. Pursuant to the terms of one of his option awards, Mr. Klein had the right to exercise that option award for shares that he was not vested in. When Mr. Klein's employment with us ended in January 2009, he held 150,000 shares of common stock that he purchased by exercising that option award, 104,166 shares of which were vested. Pursuant to the term of the option award, we have the right, but not the obligation, to repurchase the 45,834 shares that he had exercised but not vested in as of the date of his termination at a cost of \$1.00 per share. Our right to repurchase the unvested shares ends in July 2009. See Management Executive Compensation Executive Employment Agreements Richard J. Klein for a description of the vesting terms of Mr. Klein's option awards.
- (5) Represents (a) 30,000 shares of common stock that Mr. Aspiri has the right to acquire from us within 60 days of March 31, 2009 pursuant to the exercise of option awards and (b) 287,857 shares of common stock held by Aspiri Enterprises LLC. Mr. Aspiri is the managing partner and a member of Aspiri Enterprises LLC.
- (6) Includes 45,000 shares of common stock that Mr. Cable has the right to acquire from us within 60 days of March 31, 2009 pursuant to the exercise of option awards.
- (7) Includes 322,188 shares of common stock held by the Demopoulos Family Trust, of which Dr. Peter A. Demopoulos is the trustee and a beneficiary along with his mother and sister. Dr. Peter A. Demopoulos disclaims beneficial ownership of the shares held by the Demopoulos Family Trust except to the extent of his pecuniary interest therein.
- (8) Includes 50,000 shares of common stock that Dr. Hood has the right to acquire from us within 60 days of March 31, 2009 pursuant to the exercise of option awards.
- (9) Represents 966,476 shares of common stock held by Aravis Venture I, L.P. Mr. Triplet holds the title of director of Aravis General Partner Ltd., which serves as general partner of Aravis Venture I, L.P. Mr. Triplet disclaims

beneficial ownership of the shares held by Aravis Venture I, L.P., except to the extent of his proportionate pecuniary interest therein.

- (10) Includes 2,545,731 shares of common stock that our executive officers and directors have the right to acquire from us within 60 days of March 31, 2009 pursuant to the exercise of option awards.

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**DESCRIPTION OF CAPITAL STOCK**

**General**

The following is a summary of the rights of our common stock and preferred stock and related provisions of our articles of incorporation and bylaws, as they will be in effect upon completion of this offering. For more detailed information, please see our articles of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus is part.

Immediately following the completion of this offering, our authorized capital stock will consist of 170,000,000 shares, each with a par value of \$0.01 per share, of which:

150,000,000 shares will be designated as common stock; and

20,000,000 shares will be designated as preferred stock.

As of March 31, 2009, there were 473 and 77 holders of record of our preferred stock and common stock, respectively, and, assuming the conversion of all outstanding shares of our convertible preferred stock into common stock, we had outstanding 28,355,306 shares of common stock. All of our outstanding shares of convertible preferred stock will automatically convert into common stock upon completion of this offering.

**Common Stock**

The holders of our common stock are entitled to one vote per share on all matters to be voted on by the shareholders. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefor. In the event we liquidate, dissolve or wind up, holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of preferred stock. Holders of common stock have no preemptive, conversion or subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are, and all shares of common stock to be outstanding upon completion of this offering will be, fully paid and nonassessable.

**Preferred Stock**

Our board of directors has the authority, without further action by the shareholders, to issue from time to time the preferred stock in one or more series, to fix the number of shares of any such series and the designation thereof and to fix the rights, preferences, privileges and restrictions granted to or imposed upon such preferred stock, including dividend rights, dividend rates, conversion rights, voting rights, rights and terms of redemption, redemption prices, liquidation preference and sinking fund terms, any or all of which may be greater than or senior to the rights of the common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and reduce the likelihood that such holders will receive dividend payments and payments upon liquidation. Such issuance could have the effect of decreasing the market price of the common stock. The issuance of preferred stock or even the ability to issue preferred stock could have the effect of delaying, deterring or preventing a change in control. We have no present plans to issue any shares of preferred stock.



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### **Warrants**

As of March 31, 2009, we had warrants outstanding to purchase an aggregate of 459,059 shares of our common stock, assuming the conversion of our convertible preferred stock into common stock, as follows:

A warrant that we assumed in connection with our acquisition of nura on August 11, 2006 to purchase 22,613 shares of our common stock with an exercise price of \$4.66 per share. This warrant will terminate upon the earlier of (a) April 26, 2015 and (b) certain acquisitions of us as described in the warrant.

Warrants issued on March 29, 2007 to purchase an aggregate of 387,030 shares of our common stock with an exercise price of \$6.25 per share. If not exercised, these warrants will terminate on the earlier of (a) completion of this offering, (b) a change of control as defined in the warrants and (c) March 28, 2012.

Warrants that we issued on September 12, 2008 to purchase up to an aggregate of 58,136 shares of our common stock with an exercise price of \$6.88 per share in connection with loans we received from BlueCrest Venture Finance Master Fund Limited. As of March 31, 2009, 49,416 shares of common stock subject to these warrants were vested and the remaining 8,720 shares were not vested. The 8,720 shares of common stock would have vested only if we borrowed additional amounts from Blue Crest on or before March 31, 2009. Because we did not borrow those additional amounts on or before March 31, 2009, these 8,720 shares will not vest. If not exercised, the warrants will terminate on the earlier of (a) completion of this offering, (b) a change of control as defined in the warrants and (c) September 12, 2018.

### **The Stanley Medical Research Institute**

Pursuant to our funding agreement with The Stanley Medical Research Institute, or SMRI, if we meet the defined clinical milestone set forth in the funding agreement, we have agreed to meet with SMRI to discuss whether SMRI will make, and whether we will accept, a further equity investment of up to \$600,000 together with grant funding of up to \$2.7 million from SMRI. This additional equity investment and grant are subject to our negotiation of mutually agreeable terms, including the price per share of the equity investment, with SMRI.

### **Registration Rights**

The holders of an aggregate of 26,527,802 shares of our common stock, or their permitted transferees, are entitled to rights with respect to the registration of these shares under the Securities Act. These rights are provided pursuant to the terms of an amended and restated investors' rights agreement between us and the holders of these shares. Holders of an aggregate of 22,550,450 of these shares, or their permitted transferees, are entitled to demand registration rights, short-form registration rights and piggyback registration rights. Holders of the remaining 3,977,352 shares, or their permitted transferees, are entitled to only piggyback registration rights. All fees, costs and expenses of underwritten registrations will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered. The holders of all of these shares are subject to lock-up agreements with us and/or the representative of the underwriters pursuant to which they have agreed not to sell these shares during the period ending at least 180 days after the date of this prospectus, see [Shares Eligible for Future Sale Lock-Up Agreements](#).

#### *Demand Registration Rights*

We will be required, upon the written request of the holders of at least 30% of our shares of common stock issued upon conversion of our convertible preferred stock, to use our best





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efforts to register all or a portion of these shares for public resale. The demand registration rights are subject to customary limitations, and we are required to effect only one demand registration pursuant to the amended and restated investors' rights agreement. We are not required to effect a demand registration prior to the expiration of the lock-up agreements with our underwriters, which continue for a period of at least 180 days after the effective date of the registration statement to which this prospectus is a part. For a description of these lock-up agreements, including the potential extension of the lock-up period for more than 180 days, please see *Shares Eligible for Future Sale Lock-Up Agreements*.

*Short-Form Registration Rights*

If we are eligible to file a registration statement on Form S-3, we will be required, upon the written request of the holders of at least 20% of these shares of our common stock, to have such shares registered by us at our expense provided that such requested registration has an anticipated aggregate offering price to the public of at least \$2.5 million and we have not already effected one short-form registration in the preceding twelve-month period.

*Piggyback Registration Rights*

If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions, we and the underwriters may limit the number of shares included in the underwritten offering if the underwriters believe that including these shares would adversely affect the offering. These registration rights have been waived with respect to this offering.

**Anti-Takeover Effects of Washington Law and our Articles of Incorporation and Bylaws**

Certain provisions of Washington law, our articles of incorporation and our bylaws contain provisions that may delay, defer or discourage another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquiror outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

*Undesignated Preferred Stock*

As discussed above, our board of directors has the ability to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management.

*Limits on Ability of Shareholders to act by Written Consent or call a Special Meeting*

Washington law limits the ability of shareholders of public companies from acting by written consent by requiring unanimous written consent for a shareholder action to be effective. This limit on the ability of our shareholders to act by less than unanimous written consent may lengthen the amount of time required to take shareholder actions. As a result, a holder controlling a majority of our capital stock who is unable to obtain unanimous written consent from all of our shareholders would not be able to amend our bylaws or remove directors without holding a shareholders meeting.



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In addition, our articles of incorporation provide that, unless otherwise required by law, special meetings of the shareholders may be called only by the chairman of the board, the chief executive officer, the president, or the board of directors acting pursuant to a resolution adopted by a majority of the board members. A shareholder may not call a special meeting, which may delay the ability of our shareholders to force consideration of a proposal or for holders controlling a majority of our capital stock to take any action, including the removal of directors.

*Requirements for Advance Notification of Shareholder Nominations and Proposals*

Our bylaws establish advance notice procedures with respect to shareholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors. The bylaws do not give the board of directors the power to approve or disapprove shareholder nominations of candidates or proposals regarding business to be conducted at a special or annual meeting of the shareholders. However, our bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

*Board Vacancies Filled only by Directors then in Office*

Vacancies and newly created seats on our board of directors may only be filled by our board of directors. Only our board of directors may determine the number of directors on our board. The inability of our shareholders to determine the number of directors or to fill vacancies or newly created seats on our board of directors makes it more difficult to change the composition of our board of directors, but these provisions may promote a continuity of existing management.

*Directors may be Removed only for Cause*

Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our voting stock.

*Board Classification*

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our shareholders. For more information on our classified board, see

Management Board of Directors. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for shareholders to replace a majority of the directors.

*No Cumulative Voting*

Our articles of incorporation provide that shareholders are not entitled to cumulate votes in the election of directors.

*Amendment of Bylaws*

Our articles of incorporation and bylaws provide that shareholders can amend our bylaws only upon the affirmative vote of the holders of at least two-thirds of our voting stock.

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*Washington Anti-Takeover Statute*

Washington law imposes restrictions on some transactions between a corporation and significant shareholders. Chapter 23B.19 of the Washington Business Corporation Act generally prohibits a target corporation from engaging in specified significant business transactions with an acquiring person. This statute could prohibit or delay the accomplishment of mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us. An acquiring person is defined as a person or group of persons that beneficially owns 10% or more of the voting securities of the target corporation. The target corporation may not engage in significant business transactions for a period of five years after the date of the transaction in which the person became an acquiring person, unless the transaction or acquisition of shares is approved by a majority of the disinterested members of the target corporation's board of directors prior to the time of acquisition. Significant business transactions include, among other things:

a merger or share exchange with, disposition of assets to, or issuance or redemption of stock to or from, the acquiring person;

a termination of five percent or more of the employees of the target corporation as a result of the acquiring person's acquisition of 10% or more of the shares; or

a transaction in which the acquiring person is allowed to receive a disproportionate benefit as a shareholder.

After the five-year period, a significant business transaction may occur, as long as it complies with fair price provisions specified in Chapter 23B.19 or is approved at a meeting of shareholders by a majority of the votes entitled to be counted within each voting group entitled to vote separately on the transaction, not counting the votes of shares as to which the acquiring person has beneficial ownership or voting control. A corporation may not opt out of this statute.

**Listing**

We have applied to have our common stock listed on the NASDAQ Global Market under the symbol OMER.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Mellon Investor Services, LLC. The transfer agent's address is 480 Washington Blvd., Jersey City, NJ 07310 and its telephone number is 1-800-522-6645.

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**SHARES ELIGIBLE FOR FUTURE SALE**

Before this offering, there has not been a public market for shares of our common stock. Future sales of substantial amounts of shares of our common stock, including shares issued upon the exercise of outstanding option awards, in the public market after this offering, or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future.

Upon the completion of this offering, a total of \_\_\_\_\_ shares of common stock will be outstanding, assuming (a) that there are no exercises of option awards after March 31, 2009, (b) no exercise of the underwriters' over-allotment option and (c) the issuance of \_\_\_\_\_ shares of common stock upon the cashless net exercise of warrants that will automatically terminate upon completion of this offering based on the assumed initial public offering price of \$ \_\_\_\_\_ per share (the mid-point of the range set forth on the cover page of this prospectus). Of these shares, all \_\_\_\_\_ shares of common stock sold in this offering by us will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by affiliates, as that term is defined in Rule 144 under the Securities Act.

The remaining \_\_\_\_\_ shares of common stock will be restricted securities, as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Subject to the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market as follows:

<b>Date</b>	<b>Number of Shares</b>
On the date of this prospectus	
Between 90 and 180 days after the date of this prospectus	
At various times beginning more than 180 days after the date of this prospectus	

In addition, as of March 31, 2009, a total of 5,441,744 shares of our common stock were subject to outstanding option awards, of which option awards to purchase \_\_\_\_\_ shares of common stock will be vested and eligible for sale 180 days after the date of this prospectus, and a total of 22,613 shares of our common stock were subject to an outstanding warrant that will be exercisable and eligible for sale 180 days after the date of this prospectus.

**Rule 144**

In general, under Rule 144, a person deemed to be one of our affiliates for purposes of the Securities Act and who owns shares that were acquired from us or an affiliate of us at least six months prior to the proposed sale is entitled to sell upon the expiration of the lock-up agreements described below, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of:

- one percent of the number of shares of common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after the offering; and

the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

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These sales are also subject to manner of sale provisions, notice requirements and the availability of current public information about us.

Under Rule 144, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares without volume limitations, subject only to the availability of current public information about us. A non-affiliated person who has beneficially owned restricted securities within the meaning of Rule 144 for at least one year is entitled to sell those shares without regard to the provisions of Rule 144.

### **Rule 701**

In general, under Rule 701 as currently in effect, any of our employees, consultants or advisors who purchase shares from us in connection with a compensatory stock or option plan or other written agreement in a transaction that was completed in reliance on Rule 701 and complied with the requirements of Rule 701 will be eligible to resell such shares 90 days after the effective date of this offering in reliance on Rule 144, but without compliance with certain restrictions, including the holding period, contained in Rule 144.

### **Lock-Up Agreements**

Each of our officers and directors, and certain of our existing shareholders and holders of options and warrants to purchase shares of our common stock, representing an aggregate of % of our outstanding shares prior to the offering, have agreed, subject to certain exceptions, not to offer, sell, contract to sell or otherwise dispose of, or enter into any transaction that is designed to, or could reasonably be expected to, result in the disposition of any shares of our common stock or other securities convertible into or exchangeable or exercisable for shares of our common stock or derivatives of our common stock owned by these persons prior to this offering or common stock issuable upon exercise of options or warrants held by these persons for a period of 180 days after the effective date of the registration statement of which this prospectus is a part without the prior written consent of Deutsche Bank Securities Inc. This consent may be given at any time without public notice. We have entered into a similar agreement with the representative of the underwriters, see Underwriters. There are no agreements between the representative and any of our shareholders or affiliates releasing them from these lock-up agreements prior to the expiration of the 180-day period.

The 180-day restricted period described in the preceding paragraph will be extended if:

during the last 17 days of the 180-day restricted period we issue an earnings release or material news, or a material event relating to us occurs; or

prior to the expiration of the 180-day restricted period we announce that we will release earnings results during the 16-day period following the last day of the 180-day period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

The lock-up restrictions will not apply to shares of common stock acquired in open-market transactions after the closing of the offering. The lock-up restrictions also will not apply to certain transfers not involving a disposition for value provided that the transferee agrees to be





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bound by these lock-up restrictions and provided no filing by any person under the Exchange Act is required or will be voluntarily made and no person will be required by law to make or voluntarily make any public announcement of the transfer. In addition, our officers, directors and certain of our existing shareholders that purchase shares of common stock pursuant to the directed share program may transfer their directed shares provided no filing by any person under the Exchange Act is required or will be voluntarily made and no person will be required by law to make or voluntarily make any public announcement of the transfer.

**Registration Statements**

We intend to file a registration statement on Form S-8 under the Securities Act covering shares of common stock subject to options outstanding reserved for issuance under our stock plans. We expect to file this registration statement after this offering. However, none of the shares registered on Form S-8 will be eligible for resale until the expiration of the lock-up agreements to which they are subject.

**Table of Contents****UNDERWRITERS**

Subject to the terms and conditions of the underwriting agreement, the underwriters named below, through their representative Deutsche Bank Securities Inc. have severally agreed to purchase from us the following respective number of shares of common stock at a public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus:

<b>Underwriter</b>	<b>Number of Shares</b>
Deutsche Bank Securities Inc.	
Wedbush Morgan Securities, Inc.	
Leerink Swann LLC	
Needham & Company, LLC	
 Total	

The underwriting agreement provides that the obligations of the several underwriters to purchase the shares of common stock offered hereby are subject to certain conditions precedent and that the underwriters will purchase all of the shares of common stock offered by this prospectus, other than those covered by the over-allotment option described below, if any of the shares are purchased.

We have been advised by the representative of the underwriters that the underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus and to dealers at a price that represents a concession not in excess of \$      per share under the public offering price. The underwriters may allow, and these dealers may re-allow, a concession of not more than \$      per share to other dealers. After the initial public offering, the representative of the underwriters may change the offering price and other selling terms.

We have granted to the underwriters an option, exercisable not later than 30 days after the date of this prospectus, to purchase up to      additional shares of common stock at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus. The underwriters may exercise this option only to cover over-allotments made in connection with the sale of the common stock offered by this prospectus. To the extent that the underwriters exercise this option, each of the underwriters will become obligated, subject to conditions, to purchase approximately the same percentage of these additional shares of common stock as the number of shares of common stock to be purchased by it in the above table bears to the total number of shares of common stock offered by this prospectus. We will be obligated, pursuant to the option, to sell these additional shares of common stock to the underwriters to the extent the option is exercised. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the      shares are being offered.

The underwriting discounts and commissions per share are equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting discounts and commissions are      % of the initial public offering price. We have agreed to pay the underwriters the following discounts and commissions, assuming either no exercise or full exercise by the underwriters of the underwriters over-allotment option:

	<b>Total Fees</b>		
	<b>Fee per share</b>	<b>Without Exercise of Over-Allotment Option</b>	<b>With Full Exercise of Over-Allotment Option</b>

Discounts and commissions paid by us	\$	\$	\$
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In addition, we estimate that our share of the total expenses of this offering, excluding underwriting discounts and commissions, will be approximately \$ .

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We have agreed to indemnify the underwriters against some specified types of liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect of any of these liabilities.

Each of our officers and directors, and certain of our existing shareholders and holders of options and warrants to purchase shares of our common stock, representing an aggregate of % of our outstanding shares prior to the offering, have agreed, subject to certain exceptions, not to offer, sell, contract to sell or otherwise dispose of, or enter into any transaction that is designed to, or could reasonably be expected to, result in the disposition of any shares of our common stock or other securities convertible into or exchangeable or exercisable for shares of our common stock or derivatives of our common stock owned by these persons prior to this offering or common stock issuable upon exercise of options or warrants held by these persons for a period of 180 days after the effective date of the registration statement of which this prospectus is a part without the prior written consent of Deutsche Bank Securities Inc. This consent may be given at any time without public notice. We have entered into a similar agreement with the representative of the underwriters except that without such consent we may grant options and sell shares pursuant to our 2008 Equity Incentive Plan, sell shares pursuant to the exercise of option awards granted pursuant to our other equity incentive plans, and we may issue a limited amount of shares of our common stock in connection with an acquisition, strategic partnership or joint venture or collaboration. There are no agreements between the representative and any of our shareholders or affiliates releasing them from these lock-up agreements prior to the expiration of the 180-day period.

The 180-day restricted period described in the preceding paragraph will be extended if:

during the last 17 days of the 180-day restricted period we issue an earnings release or material news, or a material event relating to us occurs; or

prior to the expiration of the 180-day restricted period we announce that we will release earnings results during the 16-day period following the last day of the 180-day period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

The lock-up restrictions will not apply to shares of common stock acquired in open-market transactions after the closing of the offering. The lock-up restrictions also will not apply to certain transfers not involving a disposition for value provided that the transferee agrees to be bound by these lock-up restrictions and provided no filing by any person under the Exchange Act is required or will be voluntarily made and no person will be required by law to make or voluntarily make any public announcement of the transfer. In addition, our officers, directors and certain of our existing shareholders that purchase shares of common stock pursuant to the directed share program may transfer their directed shares provided no filing by any person under the Exchange Act is required or will be voluntarily made and no person will be required by law to make or voluntarily make any public announcement of the transfer.

## **Listing**

We have applied to list our common stock on the NASDAQ Global Market under the symbol OMER.

## **Stabilization**

In connection with this offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, purchases to cover positions created by short sales and stabilizing

transactions.

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Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. Covered short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of common stock from us in the offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option.

Naked short sales are any sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if underwriters are concerned that there may be downward pressure on the price of the shares in the open market prior to the completion of the offering.

Stabilizing transactions consist of various bids for or purchases of our common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may impose a penalty bid. This occurs when a particular underwriter repays to the other underwriters a portion of the underwriting discount received by it because the representative of the underwriters have repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions may have the effect of preventing or slowing a decline in the market price of our common stock. Additionally, these purchases, along with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the NASDAQ Global Market or otherwise and, if commenced, may be discontinued at any time.

In connection with this offering, some underwriters may also engage in passive market making transactions in our common stock on the NASDAQ Global Market. Passive market making consists of displaying bids on the NASDAQ Global Market limited by the prices of independent market makers and effecting purchases limited by those prices in response to order flow. Rule 103 of Regulation M promulgated by the SEC limits the amount of net purchases that each passive market maker may make and the displayed size of each bid. Passive market making may stabilize the market price of our common stock at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

The representative of the underwriters has informed us that the underwriters do not intend to make sales to discretionary accounts in excess of five percent of the total number of shares of common stock offered by them.

**Directed Share Program**

At our request, the underwriters have reserved for sale at the initial public offering price up to \_\_\_\_\_ shares of our common stock being sold in this offering for our directors, employees, family members of directors and employees and other third parties. The number of shares of our common stock available for the sale to the general public will be reduced to the extent these reserved shares are purchased. Any reserved shares not purchased by these persons will be offered by the underwriters to the general public on the same basis as the other shares in this offering.

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**Initial Public Offering Price**

Prior to this offering, there has been no public market for our common stock. Consequently, the initial public offering price of our common stock will be determined by negotiation among us and the representative of the underwriters. Among the primary factors that will be considered in determining the public offering price are:

prevailing market conditions;

our results of operations in recent periods;

the present stage of our development;

the market capitalizations and stages of development of other companies that we and the representative of the underwriters believe to be comparable to our business; and

estimates of our business potential.

There can be no assurance that the initial public offering price of our common stock will correspond to the price at which our common stock will trade in the public market subsequent to this offering or that an active public market for our common stock will develop and continue after this offering.

**Other Relationships**

From time to time in the ordinary course of their respective business, certain of the underwriters and their affiliates may in the future engage in commercial banking or investment banking transactions with us and our affiliates.

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**MATERIAL UNITED STATES FEDERAL TAX CONSIDERATIONS  
FOR NON-UNITED STATES HOLDERS OF COMMON STOCK**

This section summarizes certain material U.S. federal income and estate tax considerations relating to the ownership and disposition of our common stock. This summary does not provide a complete analysis of all potential tax considerations. The information provided below is based on provisions of the Code, and U.S. Treasury regulations promulgated thereunder, administrative rulings and judicial decisions currently in effect. These authorities may change at any time, possibly on a retroactive basis, or the Internal Revenue Service, or the IRS, might interpret the existing authorities differently. In either case, the tax considerations of owning or disposing of our common stock could differ from those described below. For purposes of this summary, a non-United States holder is any holder other than a citizen or resident of the United States, a corporation organized under the laws of the United States, or any state or the District of Columbia, a trust that is (a) subject to the primary supervision of a U.S. court and the control of one of more U.S. persons or (b) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person or an estate whose income is subject to U.S. federal income tax regardless of source.

If you are an individual, you may, in many cases, be deemed to be a resident of the United States, as opposed to a nonresident alien, by virtue of being present in the United States for at least 31 days in the calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. For these purposes, all the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year are counted. Resident aliens are subject to U.S. federal income tax as if they were U.S. citizens. A resident alien is urged to consult his or her own tax advisor regarding the U.S. federal income tax consequences of the sale, exchange or other disposition of common stock. If a partnership or other flow-through entity is a beneficial owner of common stock, the tax treatment of a partner in the partnership or an owner of the entity will depend upon the status of the partner or other owner and the activities of the partnership or other entity. This summary generally does not address tax considerations that may be relevant to particular investors because of their specific circumstances, or because they are subject to special rules, including if the holder is a U.S. expatriate, controlled foreign corporation, passive foreign investment company, corporation that accumulates earnings to avoid U.S. federal income tax financial institution, insurance company, broker, dealer or trader in securities, commodities or currencies, tax-exempt organization, tax-qualified retirement plan, person subject to the alternative minimum tax, or person holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy. Finally, this summary does not describe the effects of any applicable foreign, state or local tax laws, or, except to the extent discussed below, the effects of any applicable gift or estate tax laws.

**INVESTORS CONSIDERING THE PURCHASE OF COMMON STOCK SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF U.S. FEDERAL INCOME AND ESTATE TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE CONSEQUENCES OF FOREIGN, STATE OR LOCAL LAWS, AND TAX TREATIES.**

**Dividends**

We have not paid, nor do we expect in the future to pay, dividends; however, any dividend paid to a non-United States holder on our common stock will generally be subject to U.S. federal withholding tax at a 30% rate. The withholding tax might not apply, however, or might apply at a reduced rate, under the terms of an applicable income tax treaty between the United States and the non-United States holder's country of residence. A non-United States holder must certify its entitlement to treaty benefits. A non-United States holder can meet this certification requirement by providing a Form W-8BEN or appropriate substitute form to us or





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our paying agent prior to the payment of dividends and must be updated periodically. If the holder holds the stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to the agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. For payments made to a foreign partnership or other flow-through entity, the certification requirements generally apply to the partners or other owners rather than to the partnership or other entity, and the partnership or other entity must provide the partners' or other owners' documentation to us or our paying agent. Special rules, described below, apply if a dividend is effectively connected with a U.S. trade or business conducted by the non-United States holder.

### **Sale of Common Stock**

Non-United States holders will generally not be subject to U.S. federal income tax on any gains realized on the sale, exchange or other disposition of common stock unless:

the gain is effectively connected with the conduct by the non-United States holder of a U.S. trade or business (in which case the special rules described below apply);

the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale, exchange or other disposition of our common stock, and certain other requirements are met;

the non-United States holder was a citizen or resident of the United States and thus is subject to special rules that apply to expatriates; or

the rules of the Foreign Investment in Real Property Tax Act, or FIRPTA, treat the gain as effectively connected with a U.S. trade or business.

The FIRPTA rules may apply to a sale, exchange or other disposition of common stock if we are, or were within five years before the transaction, a U.S. real property holding corporation, or USRPHC. In general, we would be a USRPHC if our U.S. real property interests comprised at least half of our assets. We do not believe that we are a USRPHC or that we will become one in the future, although there can be no assurance that this conclusion is correct or might not change in the future based on changed circumstances.

### **Dividends or Gain Effectively Connected With a U.S. Trade or Business**

If any dividend on common stock, or gain from the sale, exchange or other disposition of common stock, is effectively connected with a U.S. trade or business conducted by a non-United States holder, then the dividend or gain will generally be subject to U.S. federal income tax at the regular graduated rates. If the non-United States holder is eligible for the benefits of a tax treaty between the United States and the holder's country of residence, any effectively connected dividend or gain would generally be subject to U.S. federal income tax only if it is also attributable to a permanent establishment or fixed base maintained by the holder in the United States. Payments of dividends that are effectively connected with a U.S. trade or business, and therefore included in the gross income of a non-United States holder, will not be subject to the 30% withholding tax. To claim an exemption from withholding, the holder must certify its qualification, which can be done by filing a Form W-8ECI. If the non-United States holder is a corporation, under certain circumstances that portion of its earnings and profits that is effectively connected with its U.S. trade or business would generally be subject to a branch profits tax. The branch profits tax rate is generally 30%, although an applicable income tax treaty might provide for a lower rate.

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**U.S. Federal Estate Tax**

The estates of nonresident alien individuals are generally subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our common stock will be U.S. situs property and therefore will be included in the taxable estate of a nonresident alien decedent. The U.S. federal estate tax liability of the estate of a nonresident alien may be affected by a tax treaty between the United States and the decedent's country of residence.

**Backup Withholding and Information Reporting**

The Code and the U.S. Treasury regulations require those who make specified payments to report the payments to the IRS. Among the specified payments are dividends and proceeds paid by brokers to their customers. The required information returns enable the IRS to determine whether the recipient properly included the payments in income. This reporting regime is reinforced by backup withholding rules. These rules require the payors to withhold tax from payments subject to information reporting if the recipient fails to cooperate with the reporting regime by failing to provide his taxpayer identification number to the payor, furnishing an incorrect identification number, or repeatedly failing to report interest or dividends on his returns. The backup withholding tax rate is currently 28%. The backup withholding rules generally do not apply to payments to corporations, whether domestic or foreign.

Payments of dividends on common stock to non-United States holders will generally not be subject to backup withholding, and payments of proceeds made to non-United States holders by a broker upon a sale of common stock will not be subject to information reporting or backup withholding, in each case so long as the non-United States holder certifies its nonresident status. The certification procedures to claim treaty benefits described under Dividends will satisfy the certification requirements necessary to avoid the backup withholding tax as well. We must report annually to the IRS any dividends paid to each non-United States holder and the tax withheld, if any, with respect to those dividends. Copies of these reports may be made available to tax authorities in the country where the non-United States holder resides.

Any amounts withheld from a payment to a holder of common stock under the backup withholding rules can be credited against any U.S. federal income tax liability of the holder and may entitle the holder to a refund, provided that the required information is furnished to the IRS.

**THE PRECEDING DISCUSSION OF U.S. FEDERAL TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE, LOCAL AND FOREIGN TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.**

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**LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Seattle, Washington. Morrison & Foerster LLP, New York, New York, will act as counsel to the underwriters. A member of Wilson Sonsini Goodrich & Rosati beneficially holds an aggregate of 3,071 shares of our common stock, which represents less than one percent of our outstanding shares of common stock.

**EXPERTS**

The consolidated financial statements of Omeros Corporation (a development-stage company) at December 31, 2008 and 2007, and for each of the three years in the period ended December 31, 2008 and for the period from June 16, 1994 (inception) through December 31, 2008, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about Omeros Corporation's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains an Internet web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the site is [www.sec.gov](http://www.sec.gov).

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