OMEROS CORP
Form 10-K
March 15, 2016

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

or

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

For the transition period from to

Commission file number: 001-34475

OMEROS CORPORATION
(Exact name of registrant as specified in its charter)

Washington (State or other jurisdiction of incorporation or organization)	91-1663741 (I.R.S. Employer Identification Number)
201 Elliott Avenue West Seattle, Washington (Address of principal executive offices)	98119 (Zip Code)

(206) 676-5000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Common Stock, $0.01 par value per share (Title of each class)	The NASDAQ Stock Market LLC (Name of each exchange on which registered)

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of the last business day of the registrant’s most recently completed second fiscal quarter was $629,477,368.

As of March 7, 2016, the number of outstanding shares of the registrant’s common stock, par value $0.01 per share, was 38,257,381.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant’s proxy statement with respect to the 2016 Annual Meeting of Shareholders to be held June 9, 2016, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant’s fiscal year ended December 31, 2015, are incorporated by reference into Part III of this Form 10-K.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act, which are subject to the "safe harbor" created by those sections for such statements. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical fact are "forward-looking statements." Terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "may," "plan," "potential," "predict," "project," "shoul similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

- our plans for sales, marketing and distribution of OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3%;
- our expectations regarding our product sales and our estimate regarding how long our existing cash, cash equivalents, short-term investments and revenues will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes under our Loan and Security Agreement, or the Oxford/EWB Loan Agreement, with Oxford Finance LLC, or Oxford, and East West Bank, or EWB;
- our ability to raise additional capital through the capital markets, including under our at-the-market equity facility with JonesTrading Institutional Services LLC, or JonesTrading, or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;
- our ability to forecast accurately wholesaler demand as well as our estimates of chargebacks and rebates, distribution fees and estimated product returns;
- our ability to enter into acceptable arrangements with potential corporate partners, including with respect to OMIDRIA;
- our expectations regarding the clinical, therapeutic and competitive benefits of OMIDRIA and our product candidates;
- our anticipation that we will rely on contract manufacturers to manufacture OMIDRIA for commercial sale and to manufacture our product candidates and our expectations regarding product supply and manufacturing of OMIDRIA;
- our expectations about the commercial competition that OMIDRIA and our product candidates, if commercialized, may face;
- our expectation that the OMIDRIAssure™ Reimbursement Services Program will increase patient access to OMIDRIA;
- our expectations regarding cost impacts resulting from hiring sales representatives from Ventiv Commercial Services, LLC;
- the extent of protection that our patents provide and that our pending patent applications will provide, if patents issue from such applications, for our technologies, programs, products and product candidates;
- whether the dosing limitations in our OMS824 program may be removed;
- our ability to design and successfully complete clinical trials and other studies for our products and product candidates and our plans and expectations regarding our clinical trials, including our clinical trials for OMS721 and for OMS824;
- the expected course and costs of existing claims, legal proceedings and administrative actions, our involvement in potential claims, legal proceedings and administrative actions, and the potential outcomes and effects of both existing and potential claims, legal proceedings and administrative actions, as well as regulatory determinations, on our business, prospects, financial condition and results of operations;
- our expectations regarding our OMS103 exclusive license agreement including, without limitation, manufacturing and commercialization of OMS103 and the commencement and subsequent continuation of product sales on which we could receive royalty revenue; and
- our expected financial position, performance, revenues, growth, expenses, magnitude of net losses and the availability of resources.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part I of this Annual Report on Form 10-K under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our other filings with the Securities and Exchange Commission, or SEC. Given these risks, uncertainties and other factors, actual results or developments anticipated may not be realized or, even if substantially

realized, they may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements, which represent our estimates and assumptions only as of the date of the filing of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable law,

including the securities laws of the United States and the rules and regulations of the SEC, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

OMEROS CORPORATION
ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2015
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PART I

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

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company committed to discovering, developing and commercializing both small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system.

Our marketed drug product OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3% was broadly launched in the U.S. in April 2015 for use during cataract surgery or intraocular lens, or IOL, replacement. OMIDRIA is derived from our proprietary PharmacoSurgery® platform, which is designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures. Our proprietary PharmacoSurgery platform is based on low-dose combinations of U.S. Food and Drug Administration-approved, or FDA-approved, therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. We expect that our near-term efforts will be focused on marketing and selling OMIDRIA commercially in the U.S. and expanding patient access to the drug.

In our pipeline we have clinical-stage development programs focused on: complement-related thrombotic microangiopathies; complement-mediated glomerulopathies; Huntington’s disease and cognitive impairment; addictive and compulsive disorders; and problems associated with urologic surgical procedures. In addition, we have a diverse group of preclinical programs and two additional platforms: one capable of unlocking new G protein-coupled receptor, or GPCR, drug targets and the other used to generate antibodies. For OMIDRIA and each of our product candidates and our programs, other than OMS103, we have retained control of all commercial rights.

PharmacoSurgery® Platform

We believe that 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, pupil constriction, muscle 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 preoperative treatments are not optimally effective because the administration of standard irrigation solution during the surgical procedure washes out preoperatively delivered drugs. In addition, current postoperative therapies are not optimally effective because the cascade and resultant inflammation, pain, pupil constriction, muscle spasm, loss of function and other problems have already begun and are difficult to reverse and manage after surgical trauma has occurred. Also, drugs that currently are delivered systemically to target these problems, such as by oral or intravenous administration, are frequently associated with adverse side-effects.

In contrast, we generate from our PharmacoSurgery platform proprietary products, such as OMIDRIA, and product candidates that are combinations of therapeutic agents designed to act simultaneously at multiple discrete targets to block preemptively the molecular-signaling and biochemical cascade caused by surgical trauma and to provide clinical benefits both during and after surgery. These products and product candidates are supplied in pre-dosed, pre-formulated, single-use containers and added to standard surgical irrigation solutions, delivered intraoperatively to the site of tissue trauma throughout the surgical procedure. This is expected to result 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 routine.

OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3%

Overview. OMIDRIA is approved by the FDA for use during cataract surgery or IOL replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain, and is approved in all EU member states plus Iceland, Lichtenstein and Norway for use during cataract surgery and other IOL replacement

procedures to maintain mydriasis (pupil dilation), to prevent miosis (pupil constriction), and to reduce postoperative eye pain. OMIDRIA is a proprietary drug product containing two active pharmaceutical ingredients, or APIs: ketorolac, an anti-inflammatory agent, and phenylephrine, a mydriatic, or pupil dilating, agent. FDA-approved drugs containing each of these APIs have been used in ophthalmological clinical practice for more than 20 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. OMIDRIA is added to standard irrigation solution used during cataract and lens replacement surgery and is delivered intracamerally, or within the anterior chamber of the eye, to the site of the surgical trauma throughout the procedure. Preventing pupil constriction is essential for these procedures and, if miosis occurs, the risk of damaging structures within the eye and other complications increases as does the operating time required to perform the procedure.

United States. We broadly launched OMIDRIA in the U.S. in April 2015 primarily through wholesalers which, in turn, sell to ambulatory surgery centers, or ASCs, and hospitals. The Centers for Medicare and Medicaid Services, or CMS, has granted transitional pass-through reimbursement status for OMIDRIA, which we expect to run until January 1, 2018. Pass-through status allows for separate payment (i.e., outside the bundled payment) under Medicare Part B for new drugs and other medical technologies that meet well-established criteria specified by federal regulations governing Medicare spending. Coverage for OMIDRIA has been confirmed for 100% of Medicare Administrative Contractors across all U.S. states and Puerto Rico. We have also confirmed coverage for OMIDRIA with nearly all of the 30 largest commercial third-party payers in the U.S. as well as a large number of regional commercial payers.

We believe that every patient, surgeon and facility should be able to access OMIDRIA. To that end, we have entered into agreements to enable discounts that do not affect average selling price, or ASP, on qualifying purchases of OMIDRIA by certain U.S. government purchasers and other eligible entities (e.g., 340B-eligible hospitals and clinics). In addition, in October 2015 we launched the OMIDRIAssure™ Reimbursement Services Program, or OMIDRIAssure. The OMIDRIAssure program services include the:

- OMIDRIAssure Information Hotline for physicians and facilities seeking personalized help and information on OMIDRIA coverage and reimbursement for patients;
- “Equal Access” Patient Assistance Program providing assistance to financially eligible uninsured or government-insured patients; and
- “We Pay the Difference” Commercial Reimbursement Program providing assistance to patients with insufficient commercial insurance.

The OMIDRIAssure coverage and reimbursement support services for surgeons and facilities remove uncertainties about coding, billing, and coverage of OMIDRIA. The “Equal Access” Patient Assistance and the “We Pay the Difference” Commercial Reimbursement Programs remove patients’ financial barriers to accessing the drug. Under the “Equal Access” program, financially eligible uninsured and government-insured patients receive OMIDRIA free of charge for use during surgery. For commercially insured patients, through our “We Pay the Difference” program we pay the facility, on behalf of the patient, the difference between the facility’s acquisition cost for OMIDRIA and the amount covered by the patient's insurance.

European Union and other International Territories. In July 2015, we received approval from the European Commission, or EC, to market OMIDRIA in all EU member states plus Iceland, Lichtenstein and Norway for use during cataract surgery and other IOL replacement procedures to maintain mydriasis (pupil dilation), to prevent miosis (pupil constriction), and to reduce postoperative eye pain. Decisions about price and reimbursement for OMIDRIA are made on a country-by-country basis and will be required before marketing may occur in a particular country. We do not expect to see sales of OMIDRIA in the EU and other international territories if we do not obtain such pricing and/or reimbursement decisions or if we are unable to enter into partnerships for the marketing and distribution of OMIDRIA. Timing of any such partnerships depends on numerous factors, including domestic sales of OMIDRIA.

Pediatric Studies. We have initiated a pediatric study for OMIDRIA in the U.S. and have discussed with the European Medicines Agency, or EMA, the design for a pediatric study for OMIDRIA in the EU, each of which may afford Omeros an additional six months of exclusivity in the U.S. and the EU, respectively, if completed in accordance with agreements with the respective regulatory agencies.

Abbreviated New Drug Application. In July 2015, we received a Notice Letter from Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC, or collectively, Par, that Par had filed with the FDA an Abbreviated New Drug Application, or ANDA, containing a Paragraph IV Certification under the Hatch-Waxman Act seeking approval to market a generic version of OMIDRIA prior to the expiration of three patents listed in the Orange Book for OMIDRIA, or the Orange Book Patents. These patents were granted following review by the U.S. Patent and Trademark Office, are presumed

to be valid under governing law, and can only be invalidated in federal court with clear and convincing evidence. We have reviewed the assertions in Par's Paragraph IV Notice Letter and believe that they do not have merit. We intend to enforce vigorously our intellectual property rights relating to OMIDRIA, including the three patents referenced in Par's Paragraph IV Notice Letter, as well as a fourth patent that issued after Par's Notice Letter in which all alleged prior art referenced by Par in its Notice Letter was cited and considered by the U.S. Patent and Trademark Office before issuance of the fourth patent, and additional patents that may issue from currently pending patent applications. Following receipt of the Paragraph IV Notice Letter, in September 2015 we filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par. For more information regarding this ANDA, see "Governmental Regulation-Abbreviated New Drug Application", and for more information regarding our patent infringement lawsuit against Par, see Part I, Item 3, "Legal Proceedings."

OMS103-Arthroscopy

OMS103, derived from our PharmacoSurgery platform, was developed for use during all arthroscopic procedures, including knee and shoulder arthroscopy, and completed Phase 3 trials in patients undergoing arthroscopic anterior cruciate ligament reconstruction and arthroscopic partial meniscectomy. OMS103 is a proprietary combination of anti-inflammatory/analgesic APIs, specifically amitriptyline, ketoprofen and oxymetazoline, each with well-known safety and pharmacologic profiles, and was designed to provide a multimodal approach to block preemptively the inflammatory cascade induced by arthroscopy. Each of the APIs are components of generic, FDA-approved drugs that have been marketed in the U.S. as over-the-counter, or OTC, or prescription drug products for over 20 years and have established and well-characterized safety profiles. One of the major challenges facing orthopedic surgeons performing arthroscopic procedures is adequately controlling the local inflammatory response to surgical trauma, particularly the inflammatory pain and swelling that are associated with detrimental effects on the long-term health of the joint. Added to standard irrigation solutions, OMS103 is delivered directly to the joint throughout arthroscopy and is designed to act simultaneously at multiple distinct targets to block preemptively the inflammatory cascade induced by arthroscopic surgery.

In June 2015, we entered into an exclusive licensing agreement, or the OMS103 Agreement, with Fagron Compounding Services, LLC, d/b/a Fagron Sterile Services, and JCB Laboratories, LLC, or collectively Fagron, an FDA-registered human drug outsourcing facility, under which Fagron is obligated to produce under Good Manufacturing Practice, or GMP, and to commercialize OMS103 in the U.S. Fagron has not performed its performance diligence obligations under the OMS103 Agreement, including initiating sales, and we are currently evaluating our options regarding the OMS103 Agreement and our OMS103 program. For a more detailed description of this agreement, see "License and Development Agreements."

Our Product Candidates and Development Programs

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

Product Candidate/Program	Targeted Procedure/Disease	Development Status	Next Expected Milestone	Worldwide Rights
Clinical Programs				
MASP-2 (OMS721) - Lectin Pathway Disorders	Atypical Hemolytic Uremic Syndrome (aHUS)	Phase 3	Initiate Phase 3 Enrollment	Omeros (In-licensed)
MASP-2 (OMS721) - Lectin Pathway Disorders	Thrombotic Microangiopathies (TMAs), including Hematopoietic Stem-Cell Transplant-Related TMAs and Thrombotic Thrombocytopenic Purpura (TTP)	Phase 2	Complete Phase 2 Trial	Omeros (In-licensed)
MASP-2 (OMS721) - Lectin Pathway Disorders	IgA Nephropathy and Other Renal Diseases	Phase 2	Complete Phase 2 Trial	Omeros (In-licensed)
PDE10 (OMS824) - CNS Disorders	Huntington's Disease	Phase 2	Begin Enrollment in Redesigned Phase 2 Clinical Trials	Omeros

PDE10 (OMS824) - CNS Disorders	Schizophrenia	Phase 2 [1]	Submit Phase 2 Clinical Trial Protocol to FDA	Omeros
PPAR (OMS405) - Addiction	Opioid and Nicotine Addiction	Phase 2	Analyze Phase 2 Data	Omeros
OMS201 - Urology	Ureteroscopy	Phase 1/2	Determine Commercialization Path	Omeros

Product Candidate/Program	Targeted Procedure/Disease	Development Status	Next Expected Milestone	Worldwide Rights
Preclinical Programs				
PDE7 (OMS527)	Addictions and Compulsive Disorders; Movement Disorders	Preclinical	Complete Human Dose-Enabling Toxicology Studies and GMP Manufacturing	Omeros (Compounds In-licensed)
Plasmin (OMS616)	Surgical and Traumatic Bleeding	Preclinical	Complete Human Dose-Enabling Toxicology Studies and GMP Manufacturing	Omeros (In-licensed)
MASP-3 (OMS906) - Alternative Pathway Disorders	Paroxysmal nocturnal hemoglobinuria (PNH) and Other Alternative Pathway Disorders	Preclinical	Complete Manufacturing Scale-up of a Clinical Candidate for IND-Enabling Toxicology Studies	Omeros
GPR17 - CNS Disorders	Demyelinating Disorders	Preclinical	Complete in vivo Proof-of-Concept Studies and Compound Optimization	Omeros
GPR101 - Metabolic Disorders	Appetite and Eating Disorders	Preclinical	Complete in vivo Proof-of-Concept Studies and Compound Optimization	Omeros
GPR151 - CNS Disorders	Neuropathic Pain and Cognition	Preclinical	Complete in vivo Proof-of-Concept Studies and Compound Optimization	Omeros
GPR161 - Cancer	Triple-Negative Breast Cancer	Preclinical	Complete in vivo Proof-of-Concept Studies and Compound Optimization	Omeros
GPR174 - Immune Disorders	Dysfunction of Regulatory T Cell (“T-Reg”) Modulation	Preclinical	Complete in vivo Proof-of-Concept Studies and Compound Optimization	Omeros
GPR183 - Skeletal and Infectious Diseases	Osteoporosis and EBV-Related Diseases	Preclinical	Complete in vivo Proof-of-Concept Studies and Compound Optimization	Omeros
GPCR Platform	CNS, Metabolic, CV, Oncologic, Musculoskeletal & Other Disorders	Preclinical	Continue Drug Discovery and Selected Medicinal Chemistry for Class A Orphan and Class B GPCRs	Omeros
Antibody Platform	Metabolic, CV, Oncologic, Musculoskeletal & Other Disorders	Preclinical	Continue Developing Antibodies Targeting Lectin and Alternative Pathway of Complement System and Expanding Antibody Library	Omeros (In-licensed)

(1)

Clinical trials evaluating OMS824 in schizophrenia were previously suspended at the request of the FDA and, given that we have not yet submitted a Phase 2 clinical trial protocol to FDA for review, remain suspended. For additional information, see “Clinical Programs-PDE10 Programs-OMS824 for Huntington’s Disease and Schizophrenia.”

Clinical Programs

MASP-2 Program - OMS721 - Lectin Pathway Disorders

Overview. Mannan-binding lectin-associated serine protease-2, or MASP-2, is a novel pro-inflammatory protein target involved in activation of the complement system, which is an important component of the immune system. The complement system plays a role in the inflammatory response and becomes activated as a result of tissue damage or trauma or microbial pathogen invasion. Inappropriate or uncontrolled activation of the complement system can cause diseases characterized by serious tissue injury. MASP-2 is recognized as the effector enzyme, and is required for the function, of the lectin pathway, one of the principal complement activation pathways. 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. We are developing MASP-2 antibodies and small molecules and we expect that the intended therapeutic effect can be achieved through multiple routes of administration, including subcutaneous and intravenous administration of our antibodies and oral and intravenous administration of our small molecules. OMS721 is our lead human monoclonal antibody targeting MASP-2. OMS721 has received Orphan Drug designation for the

prevention (inhibition) of complement-mediated TMAs, and Fast Track designation for the treatment of patients with aHUS.

OMS721 is being developed for diseases in which the lectin pathway is believed to contribute to significant tissue injury and pathology. One group of such diseases is TMAs, including aHUS, TTP and hematopoietic stem-cell transplant, or HSCT, -related TMA. These diseases are typically characterized by significant kidney or central nervous system injury when not treated. We recently initiated a Phase 3 clinical program in patients with aHUS and are currently conducting two Phase 2 clinical programs, one in patients with TMAs (i.e., HSCT-related TMA and TTP) and a second in patients with immunoglobulin A, or IgA, nephropathy and other complement-related renal diseases (e.g., membranous nephropathy, lupus nephritis and C3 glomerulopathy).

The Phase 3 program consists of one clinical trial - a single-arm (i.e., no control arm), open-label trial in patients with newly diagnosed or ongoing aHUS. The clinical package for the Biologics License Application, or BLA, will be similar to that which formed the basis of approval for Soliris® (eculizumab). We also received agreement from FDA on our ongoing manufacturing for both the Phase 3 program and commercialization of OMS721 as well as on our nonclinical safety and toxicology plan, most of which has already been successfully completed with no significant adverse findings. We expect that Phase 3 enrollment will begin later this year and that patients currently being treated in the Phase 2 trial will be included in the Phase 3 program. We plan to pursue accelerated approval from the FDA for OMS721 in aHUS.

In addition to TMAs and renal disease, many other disorders have evidence of lectin pathway injury, and we plan to evaluate OMS721 in one or more of them.

Clinical Trial Results. The first OMS721 Phase 2 clinical trial is evaluating the effects of the drug on patients with complement-mediated TMAs. This trial consists of three stages. The first stage is a three-level dose-ranging stage, and patient dosing has been completed. The second and third stages are fixed-dose stages and are currently in progress. Initially, the Phase 2 TMA program included aHUS, HSCT-related TMA and TTP patients. Following a recent meeting with the FDA, a Phase 3 clinical program was initiated in aHUS patients. The Phase 2 TMA program has continued, focused on HSCT-related TMA and TTP patients.

In February 2015, we announced the completion of dosing of the low-dose cohort of patients in Stage 1 of the Phase 2 clinical trial. This first cohort consisted of three aHUS patients treated with the lowest dose of OMS721. All patients in this study cohort received OMS721 and improvements were observed in TMA disease markers.

In August 2015, we announced positive data from the mid- and high-dose cohorts in the dose-ranging stage of our Phase 2 clinical trial for the treatment of TMAs with consistent and robust improvement in efficacy measures. As in the low-dose cohort, OMS721 was well tolerated by all patients in the mid- and high-dose cohorts throughout the treatment period. In the mid-dose cohort, the two patients with plasma therapy-resistant aHUS demonstrated clinically meaningful improvements in blood measures of aHUS activity.

The high-dose cohort enrolled two aHUS patients. One was plasma therapy-resistant with additional complicating disorders including hepatitis C, cryoglobulinemia and lymphoma. Prior to OMS721 treatment, the patient required repeated dialysis. Throughout treatment and through follow-up, the patient remained off dialysis. Hematological and renal parameters showed substantial improvement. The other patient was plasma therapy-responsive. She required plasma therapy twice weekly. The patient's aHUS flared when she attempted to decrease her plasma therapy to once weekly. Following treatment with OMS721, the patient's aHUS remitted and she has remained stable on plasma therapy once weekly. Two patients with HSCT-related TMA were enrolled in the high-dose cohort of Stage 1 of the Phase 2 clinical trial. One patient has a history of lymphoma and underwent HSCT complicated by a number of life-threatening disorders, including TMA. The patient showed significant improvement in TMA disease markers following OMS721 treatment. One other patient with HSCT-associated TMA enrolled in the high-dose cohort of Stage 1. This patient enrolled in the trial when his renal function had severely deteriorated. He discontinued the study early when no improvement in disease markers was observed.

There have been multiple requests from investigators and other physicians for expanded access to OMS721, including two study patients suffering from aHUS and access to OMS721 for compassionate use was provided. One of these patients was on dialysis, but was not eligible for kidney transplant because her aHUS was active. Her condition stabilized on OMS721 and her investigator considers her eligible for transplantation. Another physician, in Finland,

has requested compassionate use of OMS721 for a patient with aHUS who did not respond adequately to Soliris® and we have agreed to make OMS721 available for this patient.

In addition to the Phase 3 clinical program in patients with aHUS, two Phase 2 clinical programs are enrolling: one in TMAs and the other in complement-related renal diseases, including IgA nephropathy.

Other Studies. We have completed a series of in vivo studies using either proprietary MASP-2 knock-out mice and/or MASP-2 antibodies in established models of disease that are linked to activation of the complement system. Our findings in those studies suggest that antibody-blockade of MASP-2 may have a preventive or therapeutic effect in the treatment of a wide range of complement-related diseases and disorders, including TMAs (e.g., aHUS, HSCT-related TMA, TTP) and renal diseases, which are the disorders targeted by our first Phase 3 clinical program and one of our two Phase 2 clinical trials. In addition, we have generated positive preclinical data in in vivo models of age-related macular degeneration, or AMD, myocardial infarction, diabetic neuropathy, stroke, ischemia-reperfusion injury, and other diseases and disorders.

Licensing Arrangements. We hold worldwide exclusive licenses to rights related to MASP-2, the antibodies targeting MASP-2 and the therapeutic applications for those antibodies from the University of Leicester, from its collaborator, Medical Research Council at Oxford University, or MRC, and from Helion Biotech ApS, or Helion. For a more detailed description of these licenses, see “License and Development Agreements.”

PDE10 Programs - OMS824 for Huntington’s Disease and Schizophrenia

Overview. Phosphodiesterase 10, or PDE10, is an enzyme that is expressed in areas of the brain strongly linked to diseases that affect cognition, including Huntington’s disease and schizophrenia. Cognitive dysfunction occurs early in these diseases and is responsible for substantial disability. PDE10 inhibitors have been shown to be effective in multiple animal models of behavior and cognition, and there remain substantial unmet clinical needs with current treatments. Our proprietary compound OMS824 inhibits PDE10 and is being developed in clinical programs for the treatment of cognitive disorders, including Huntington’s disease and schizophrenia. In Huntington’s disease, OMS824 may improve motor and behavioral abnormalities as well as cognition. In schizophrenia, OMS824 may have, in addition to cognitive enhancement, beneficial effects on the positive (e.g., hallucinations) and negative (e.g., flat affect) symptoms of the disease. OMS824 may address other limitations of current treatments for both schizophrenia and Huntington’s disease, for example, by avoiding the weight gain, hyperlipidemia, and the risk of sudden cardiac death associated with current antipsychotic medications as well as the depression and suicidal ideation seen with tetrabenazine, the only FDA-approved treatment for Huntington’s disease.

OMS824 has received Orphan Drug designation for the treatment of Huntington’s disease and Fast Track designation for the treatment of cognitive impairment in patients with Huntington’s disease.

Clinical Trials. OMS824 is in a Phase 2 clinical program for the treatment of Huntington’s disease and a Phase 2 clinical program evaluating OMS824 for the treatment of schizophrenia. Clinical trials in our Huntington’s program are currently subject to dosing limitations. The dosing limitations may potentially be removed pending generation, submission and FDA review of additional information. We are conducting nonclincal studies to generate additional data for further discussion with the FDA regarding the dosing limitations and are currently preparing for a re-designed Phase 2 clinical trial in patients with Huntington’s disease.

In our schizophrenia program, we have completed a Phase 2a trial evaluating OMS824’s tolerability, safety, pharmacokinetics, potential interactions with concomitant antipsychotic medications, and potential effects on cognition using a battery of cognitive tests in patients with schizophrenia. The drug was well tolerated in this trial and demonstrated comparable systemic pharmacokinetics when administered alone and concomitantly with approved antipsychotic agents. As we announced in October 2014, clinical trials evaluating OMS824 in schizophrenia are suspended currently at the request of the FDA. Given that there was no active schizophrenia trial at the time of program suspension, the FDA will address the OMS824 schizophrenia program when we have a related trial protocol ready for initiation.

Funding Agreement with The Stanley Medical Research Institute. Our preclinical development of OMS824 was supported by funds from The Stanley Medical Research Institute, or SMRI, a non-profit corporation that supports research on the causes and treatment of schizophrenia and bipolar disorder. For a more detailed description of our agreement with SMRI, see “License and Development Agreements.”

PPAR Program - OMS405

Overview. In our peroxisome proliferator-activated receptor gamma, or PPAR , program, we are developing proprietary compositions that include PPAR agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine and alcohol. We believe that Omeros is the first to demonstrate a link

between PPAR and addiction disorders. Data from European pilot clinical studies and animal models of addiction suggest that PPAR agonists could be efficacious in the treatment of a wide range of addictions.

Clinical trials. Our collaborators at The New York State Psychiatric Institute have completed two Phase 2 clinical trials related to our PPAR program. These studies evaluated a PPAR agonist, alone or in combination with other agents,

for treatment of addiction to opioids and to nicotine. Our collaborators are analyzing data from these trials and expect to present relevant information in manuscripts to be published at a later date. The National Institute on Drug Abuse provided substantially all of the funding for these clinical trials and solely oversaw the conduct of these trials. We have the right or expect to be able to reference the data obtained from these studies for subsequent submissions to the FDA, and continue to retain all other rights in connection with the PPAR program.

Patent Assignment Agreement with Roberto Ciccocioppo, Ph.D. We acquired the patent applications and related intellectual property rights for our PPAR program in February 2009 from Roberto Ciccocioppo, Ph.D., of the Università di Camerino, Italy, pursuant to a patent assignment agreement. For a more detailed description of our agreement with Dr. Ciccocioppo, see "License and Development Agreements."

OMS201-Urology

Overview. OMS201 is our PharmacoSurgery product candidate designed for use during urological procedures, including ureterscopy for removal of ureteral or renal stones. OMS201 is a proprietary combination of ketoprofen, an anti-inflammatory API, and nifedipine, a smooth muscle relaxant API. Each API is contained in generic, FDA-approved drugs that have been marketed in the U.S. for more than 20 years and have well-known safety and pharmacologic profiles. Both of these APIs have been individually prescribed to manage the symptoms of ureteral and renal stones.

Uroendoscopic procedures are performed within the urinary tract using a flexible camera device, or endoscope, and cause tissue injury that activates local mediators of pain and inflammation, which results in inflamed tissue, pain, smooth muscle spasm and lower urinary tract symptoms including frequency, urgency and painful urination, and can prolong recovery. Added to standard irrigation solutions in urological surgery, OMS201 is designed 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.

In 2010, we completed a Phase 1/Phase 2 clinical trial in 24 patients designed to evaluate the safety and systemic absorption of two sequentially higher concentrations of OMS201 added to standard irrigation solution and delivered to patients undergoing ureteroscopy for removal of ureteral or renal stones. OMS201 was well tolerated in this study. The next step in our OMS201 program is to design a Phase 2 clinical program; however, the program is on hold given current availability of clinical development resources. We are evaluating alternative approaches to make OMS201 commercially available, such as through a registered outsourcing facility without the need to conduct any additional clinical trials.

Preclinical Programs

PDE7 Program - OMS527

Overview. Our phosphodiesterase 7, or PDE7, program is based on our discoveries of previously unknown links between PDE7 and any addiction or compulsive disorder and between PDE7 and any movement disorders, such as Parkinson's disease. PDE7 appears to modulate the dopaminergic system, which plays a significant role in regulating both addiction and movement. We believe that PDE7 inhibitors could be effective therapeutics for the treatment of addiction and compulsive disorders as well as for movement disorders. Data generated in preclinical studies support the use of PDE7 inhibitors in both of these therapeutic areas. We have selected a clinical candidate and are preparing to initiate toxicology studies under good laboratory practices, or GLP, intended to support the submission of an Investigational New Drug application, or IND, or clinical trial application, or CTA, and subsequent clinical trials.

Exclusive License Agreement with Daiichi Sankyo Co., Ltd. We hold an exclusive license to certain PDE7 inhibitors claimed in patents and pending patent applications owned by Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.), or Daiichi Sankyo, for use in the treatment of movement, addiction and compulsive disorders as well as other specified indications. For a more detailed description of our agreement with Daiichi Sankyo, see "License and Development Agreements."

Plasmin Program - OMS616

Overview. In our plasmin program, we are advancing novel antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma as well as for other hyperfibrinolytic states (e.g., liver disease). Excessive bleeding during cardiac or trauma surgery is known to increase overall morbidity and mortality. In an attempt to control this

bleeding, patients undergoing cardiac and other extensive surgery often receive antifibrinolytic compounds. These drugs inhibit plasmin, an enzyme present in blood that degrades fibrin clots. Because plasmin degrades fibrin clots, an agent that inhibits plasmin may have potential utility for reducing blood loss due to trauma or surgery.

Prior to withdrawal from the U.S. and European markets in 2008 for safety concerns, the antifibrinolytic Trasylol® (aprotinin) had been shown in a number of studies to be more effective at reducing blood loss than the other two most commonly used antifibrinolytics on the market today, tranexamic acid and epsilon aminocaproic acid. While Trasylol® is a potent inhibitor of plasmin, it is non-selective. In addition to plasmin, it significantly inhibits kallikrein and Factor XIa, two enzymes important in promoting clotting, and their inhibition can increase bleeding. Trasylol® was found to be associated with a number of safety issues, including increased mortality. Further, it is a bovine protein associated with anaphylactic reactions. While the specific cause of increased death remains unknown, an often-cited explanation is the lack of specificity of Trasylol®.

Our proprietary agents also inhibit plasmin but, unlike Trasylol®, they do not significantly inhibit kallikrein or Factor XIa. Additionally, our agents are derived from human protein, which may reduce immunological side effects. The properties of our proprietary agents are described in a peer-reviewed article titled “Engineering Kunitz Domain 1 (KD1) of Human Tissue Factor Pathway Inhibitor-2 to Selectively Inhibit Fibrinolysis: Properties of KD1-L17R Variant” that was published in the February 11, 2011 issue of the Journal of Biological Chemistry. We believe that the potential efficacy, human-protein derivation and improved selectivity of our proprietary agents provide a novel approach to the control of bleeding from surgery and trauma.

We are in the process of manufacturing preclinical supplies to enable the initiation of GLP toxicology studies intended to support the submission of an IND or CTA and subsequent clinical trials. Ex vivo studies in human plasma comparing the efficacy of our lead clinical candidate to that of Trasylol® in inhibiting plasmin demonstrated that, in these studies, our candidate was at least as effective as Trasylol®. Given that our molecule is (1) a human-derived protein rather than bovine-derived as is Trasylol® and (2) does not have the off-target activity seen with Trasylol® against kallikrein and Factor XIa, we expect that our molecule will compare favorably to Trasylol® with respect to safety. This expectation will need to be borne out by clinical trials.

Exclusive License Agreement with The Regents of the University of California. We hold a worldwide exclusive license to patent rights related to certain antifibrinolytics from The Regents of the University of California. For a more detailed description of this agreement, see “License and Development Agreements.”

MASP-3 Program - OMS906 - Alternative Pathway Disorders

Overview. As part of our MASP program, we have identified mannan-binding lectin-associated serine protease-3, or MASP-3, as what we believe is the key activator of the alternative pathway of the complement system, and we believe that we are the first to make this and related discoveries associated with the alternative pathway. The complement system is part of the immune system’s innate immune response, and the alternative pathway is considered the amplification loop within the complement system. Based on our alternative pathway-related discoveries, we have expanded our intellectual property position to protect our inventions stemming from these discoveries beyond MASP-2-associated inhibition of the lectin pathway to include inhibition of the alternative pathway. In addition to our MASP-2 inhibitors of the lectin pathway, we are developing inhibitors of the alternative pathway as well as bispecific inhibitors of both the alternative and lectin pathways. For each of these targets, our efforts are directed to both antibody and small-molecule development.

We are currently developing MASP-3 inhibitors for the treatment of disorders related to the alternative pathway of the complement system and are optimizing potent and functionally active antibodies in preparation for scale-up of one or more clinical candidates. We believe that MASP-3 inhibitors may have the potential to treat subjects suffering from a wide range of diseases and conditions, including paroxysmal nocturnal hemoglobinuria, or PNH, asthma, traumatic brain injury, AMD, disseminated intravascular coagulation, arthritis, dense deposit disease, aspiration pneumonia, neuromyelitis optica, pauci-immune necrotizing crescentic glomerulonephritis, endophthalmitis and Behcet’s disease.

Licensing Arrangements. We jointly own and hold worldwide exclusive license rights related to therapeutic applications for inhibiting MASP-3 from the University of Leicester. For a more detailed description of these licenses, see “License and Development Agreements.”

GPCR Platform

Overview. GPCRs comprise one of the largest families of proteins in the genomes of multicellular organisms. It is estimated that there are over 1,000 GPCRs in the human genome, comprising three percent of all human proteins. GPCRs are cell surface membrane proteins involved in mediating both sensory and nonsensory functions. Sensory

GPCRs are involved in the perception of light, odors, taste and sexual attractants. Non-sensory GPCRs are involved in metabolism, behavior, reproduction, development, hormonal homeostasis and regulation of the central nervous system. The vast majority of GPCR drug targets are non-sensory. Although GPCRs form a super-family of receptors, individual GPCRs

display a high degree of specificity and affinity for the functionally active molecules, or ligands, that bind to a given receptor. Ligands can either activate the receptor (agonists) or inhibit it (antagonists and inverse agonists). When activated by its ligand, the GPCR interacts with intracellular G proteins, resulting in a cascade of signaling events inside the cell that ultimately leads to the particular function linked to the receptor.

The high degree of specificity and affinity associated with GPCRs has contributed to their becoming the largest family of drug targets for therapeutics against human diseases. It is estimated that nearly 40% of all drugs sold worldwide target GPCRs, yet only 46 GPCRs are responsible for this wealth of drugs. Based on available data, we believe that there are 363 human non-sensory GPCRs, of which approximately 120 have no known ligands, and we refer to those receptors as orphan GPCRs. Without a known ligand, there is no template from which medicinal chemistry efforts can be readily initiated nor a means to identify the GPCR's signaling pathway and, therefore, drugs are very difficult to develop against orphan GPCRs. "Unlocking" these orphan GPCRs by identifying one or more of their respective ligands could lead to the development of drugs that act at these new targets. To our knowledge, despite efforts by others in the biopharmaceutical industry and academic community, Omeros' technology is the first commercially viable technology capable of identifying ligands of orphan GPCRs in high throughput.

We have developed a proprietary cellular redistribution assay, or CRA, which we use in a high-throughput manner to identify synthetic ligands, including antagonists, agonists and inverse agonists, that bind to and affect the function of orphan GPCRs. We believe that we are the first to possess the capability to conduct high-throughput drug discovery for orphan GPCRs and that there is no other existing high-throughput technology able to "unlock" orphan GPCRs. We have screened Class A orphan GPCRs against our small-molecule chemical libraries using the CRA. As of February 29, 2016, we had identified and confirmed compounds that interact with 54 of the 81 Class A orphan GPCRs linked to a wide range of indications including cancer as well as metabolic, cardiovascular, immunologic, inflammatory and central nervous system disorders. In addition to GPR17, discussed below, we have initiated medicinal chemistry efforts to optimize compounds against several orphan GPCRs including: GPR101, linked to appetite and eating disorders; GPR151, linked to neuropathic pain and cognition; GPR161, which is associated with triple negative breast cancer; GPR183, linked to osteoporosis and to Epstein-Barr virus infections and related diseases; and GPR174, which appears to be involved in the modulation of regulatory T cells, or "T-regs," known to be important in autoimmune disease, such as multiple sclerosis, and in cancer and organ transplantation.

In addition to Class A orphan GPCRs, we have also begun screening orphan and non-orphan Class B receptors. Class B GPCRs have large extracellular domains and their natural ligands are generally large peptides, making the development of orally active, small-molecule drugs against these receptors, such as glucagon and parathyroid hormone, a persistent challenge. Despite the fact that oral agents are not available, the current sales for the commercialized Class B GPCR-targeting peptide drugs are large. Our CRA technology finds functionally active small molecules for GPCRs, which we believe could lead to the development of oral medications for many of the Class B GPCRs. While our focus to date has remained on Class A orphan GPCRs and, as of February 29, 2016, we had identified and confirmed sets of compounds that interact selectively with, and modulate signaling of, a small subset of Class B GPCRs, namely glucagon-like peptide-1 receptor, or GLP-1R, and parathyroid hormone 1 receptor, or PTH-1R.

GPCR Platform Funding Agreements with Vulcan Inc. and the Life Sciences Discovery Fund. In October 2010, we entered into funding agreements for our GPCR program with Vulcan Inc. and its affiliate, which we refer to collectively as Vulcan, and with the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or LSDF. For a more detailed description of these agreements, see "License and Development Agreements."

GPR17 Program

We are conducting medicinal chemistry to optimize compounds against GPR17, a GPCR that is linked to myelin formation. Myelin is an insulating layer rich in lipids and proteins that forms a sheath around the nerve fibers, which is essential for the proper functioning of the nervous system. Loss of the myelin sheath is the hallmark of several diseases, including multiple sclerosis, acute disseminated encephalomyelitis, neuromyelitis optica, transverse myelitis, chronic inflammatory demyelinating polyneuropathy, Guillain-Barré syndrome, central pontine myelinosis and inherited demyelinating diseases such as leukodystrophy and Charcot-Marie-Tooth disease. We believe GPR17

inhibitors have the potential to promote remyelination and improve the outcome of these diseases as well as of traumatic brain injury and spinal cord injury, conditions that have been associated with GPR17. Discovering GPR17 inhibitors has previously been challenging to the pharmaceutical industry because this receptor is an orphan GPCR, i.e., its natural ligand is not known, as discussed above. However, using our proprietary cellular redistribution assay, which allows compound screening against orphan GPCRs without knowledge of a given receptor's natural ligand, we have been able to identify a large number of compounds that functionally interact with GPR17. In vivo animal studies have been conducted and others are in progress, and we continue addition to medicinal chemistry efforts to optimize compounds against GPR17, and compound optimization is ongoing.

GPR101 Program

We are conducting medicinal chemistry to optimize compounds against GPR101, a GPCR that is linked to appetite and eating disorders. We believe GPR101 modulators have the potential to impact appetite and food consumption and improve conditions such as obesity, diabetes, insulin resistance, metabolic syndrome, eating disorders (e.g., anorexia nervosa or hyperphagia), or cachexia (also known as wasting syndrome). We have been able to identify a large number of compounds that functionally interact with GPR101. In vivo animal studies have been conducted and others are in progress.

GPR151 Program

We are conducting medicinal chemistry to optimize compounds against GPR151, a GPCR that is linked to neuropathic pain and cognitive disorders. We believe GPR151 modulators have the potential to improve the outcome of individuals suffering from neuropathic pain and cognitive impairment such as memory loss, dementia, and learning disabilities. We have been able to identify a large number of compounds that functionally interact with GPR151. In vivo animal studies are ongoing.

GPR161 Program

We are conducting medicinal chemistry to optimize compounds against GPR161, a GPCR that is linked to triple negative breast cancer, or TNBC, and sarcomas. We believe GPR161 modulators have the potential to improve the outcome of individuals with TNBC, an aggressive form of breast cancer that does not express the genes for estrogen receptor, progesterone receptor or Her2/neu. GPR161 modulators also hold promise for patients with sarcomas, such as osteosarcoma, chondrosarcoma, and leiomyosarcoma. We have been able to identify a large number of compounds that functionally interact with GPR161. In vivo animal studies have been conducted and others are in progress.

GPR174 Program

We are conducting medicinal chemistry to optimize compounds against GPR174, a GPCR that is linked to autoimmunity. We believe GPR174 modulators have the potential to improve the outcome of individuals suffering from autoimmune disorders such as multiple sclerosis, psoriasis, ulcerative colitis, systemic lupus erythematosus and rheumatoid arthritis. We have been able to identify a large number of compounds that functionally interact with GPR174. In vivo animal studies are in progress.

GPR183 Program

We are conducting medicinal chemistry to optimize compounds against GPR183, a GPCR that is linked to osteoporosis and Epstein-Barr virus, or EBV, infections and associated diseases. We believe GPR183 modulators have the potential to improve the outcome of osteoporosis as well as of individuals suffering from EBV infections and associated diseases, such as mononucleosis, post-transplant lymphoproliferative disorders and nasopharyngeal carcinoma. We have been able to identify a large number of compounds that functionally interact with GPR183. In vivo animal studies have been conducted and others are in progress.

Antibody Platform

Overview. Our proprietary ex vivo platform for the discovery of novel, high-affinity monoclonal antibodies, which was in-licensed from the University of Washington and then further developed by our scientists, utilizes a chicken B-cell lymphoma cell line. It has successfully generated diverse antibodies that can be readily engineered. This platform offers several advantages over other antibody platforms. The ex vivo immunizations of our proprietary cell line are significantly more rapid than whole animal immunizations and conventional hybridoma technology. By avoiding immunization of mice or other animals, we believe the antibodies we generate from this platform are not limited by immunological tolerance. In addition, our platform is capable of producing novel antibodies against difficult targets, such as highly homologous proteins, enzymes, and receptors with short extracellular domains. Chicken antibodies also have unique features that enable binding capabilities distinct from mammalian antibodies. We have generated antibodies to several clinically significant targets, including highly potent antibodies against MASP-3, and our platform continues to add to our pipeline antibodies against additional important targets.

Asset Purchase Agreement with Xori Corporation. In February 2012 we entered into an Asset Purchase Agreement, or the Xori APA, with Xori Corporation, or Xori, pursuant to which we acquired all of Xori's rights and obligations in certain license and material transfer agreements, intellectual property, antibodies and other assets related to our antibody platform. We are obligated to make development and research-related milestone payments to Xori.

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Exclusive License Agreement with the University of Washington. We hold a worldwide exclusive license to patent rights related to our antibody platform from the University of Washington. For a more detailed description of this agreement, see “License and Development Agreements.”

Sales and Marketing

Overview. We have retained all worldwide marketing and distribution rights to OMIDRIA, our product candidates and our development programs, other than OMS103. This allows us the opportunity to market and sell independently OMIDRIA or, if approved, any of our product candidates, to make arrangements with third parties to perform these services for us, or both.

OMIDRIA. With respect to OMIDRIA, we have developed our own internal marketing and sales capabilities. Prior to January 1, 2016, in the U.S. we utilized a dedicated contract sales organization. Effective January 1, 2016, we converted the contract sales force to Omeros employees and employ 37 in-house sales representatives as of March 8, 2016. We also use the services of Precision Lens under a commission-only arrangement to cover territories in the Midwest that are not covered by our in-house sales force. Because surgeons specializing in cataract surgery are a sub-specialty within ophthalmology, we believe that we can effectively access high-volume surgeons with our existing sales organization and the services of third-party sales agents such as Precision Lens in certain territories in the U.S. In the EU, we plan to out-license OMIDRIA marketing and distribution rights to one or more third parties that have capabilities to promote to ophthalmologic surgeons, to facilitate distribution and reimbursement, and to manage pharmacovigilance and clinical support. Outside of the U.S. and EU, we are exploring potential regional partnerships to make OMIDRIA available to ophthalmologists. We have not yet entered into any agreements with third parties to market OMIDRIA outside of the U.S. If we are unable to enter into one or more such agreements on terms acceptable to us, we would not expect to see sales of OMIDRIA in those territories.

OMS103. Our OMS103 Agreement with Fagron requires Fagron to meet performance diligence requirements including to bear all sales and marketing costs for U.S. sales. We have retained marketing and distribution rights for OMS103 outside of the U.S. Fagron has not performed its performance diligence obligations under the OMS103 Agreement, including initiating sales. For a more detailed description of our agreement with Fagron and Fagron’s non-performance, see “License and Development Agreements.”

Manufacturing, Supply and Commercial Operations

OMIDRIA. We use third parties to produce, store and distribute OMIDRIA and currently do not own or operate manufacturing facilities. Our agreements with these third parties include confidentiality and intellectual property provisions to protect our proprietary rights related to OMIDRIA. We require manufacturers that produce APIs and finished drug products to operate in accordance with current Good Manufacturing Practices, or cGMPs, and all other applicable laws and regulations.

We have agreements with Patheon Manufacturing Services, LLC (successor-in-interest to DSM Pharmaceuticals, Inc.), or Patheon, and with Hospira Worldwide, Inc., or Hospira, pertaining to commercial supply of OMIDRIA. Commercial manufacturing of OMIDRIA under our agreement with Patheon, or the Patheon Agreement, ceased on December 31, 2015 in accordance with the terms of the Patheon Agreement with the exception of the final delivery of product as further described in Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations--Contractual Obligations and Commitments.” With respect to Hospira, we are currently completing the manufacturing process transfer, process validation and approval of Hospira as a manufacturing site for OMIDRIA. Until this process is complete, Hospira may not manufacture and supply OMIDRIA. We do not expect the process validation for OMIDRIA at a Hospira facility to be completed earlier than the second half of 2016. As a result, we expect that OMIDRIA manufacturing will be approved for production some time in the first part of 2017. We anticipated this interruption in manufacturing and increased production of OMIDRIA prior to the break in manufacturing. We believe that we will have sufficient supply to meet product needs until OMIDRIA product production is recommenced.

Under the agreement with Hospira, or the Hospira OMIDRIA Agreement, Hospira has agreed to manufacture and supply, and we have agreed to purchase, a minimum percentage of our requirements of OMIDRIA for commercial sales and clinical supplies for the development of additional therapeutic indications in the U.S. In addition, Hospira has agreed to manufacture and supply a portion of our requirements of OMIDRIA in the EU in an amount to be

mutually agreed by the parties (not to exceed a maximum percentage of our EU requirements), with there being no minimum purchase and supply requirement in the EU if the parties do not reach agreement during such time period and the agreement is not amended thereafter. The Hospira OMIDRIA Agreement has an initial term of five years from the date of first commercial sale of

OMIDRIA in the U.S. or in any country in the EU, and thereafter is renewed automatically for up to two additional one-year periods. The Hospira OMIDRIA Agreement may be terminated prior to the end of its term upon the occurrence of certain specified events, including without limitation an uncured breach of the agreement or bankruptcy or dissolution of a party. Upon termination of the Hospira OMIDRIA Agreement, except in the case of termination for an uncured breach by Hospira, we will be required to purchase all of Hospira's inventory of OMIDRIA and, if applicable, all work-in-progress inventory and to reimburse Hospira for all supplies purchased or ordered based on firm purchase orders or our estimates of its requirements of OMIDRIA.

We have used multiple suppliers for the OMIDRIA APIs. Given the large amount of these APIs manufactured annually by these and other suppliers, and the quantities of these APIs we have on hand, we anticipate that we will be capable of addressing our commercial API supply needs for OMIDRIA. We have not yet signed commercial agreements with suppliers for the supply of all of our anticipated commercial quantities of these APIs for OMIDRIA, although we may elect to do so in the future.

In the U.S., we sell OMIDRIA through a limited number of wholesalers that distribute the product to ASCs and hospitals. Title transfers upon delivery of OMIDRIA to the wholesaler. We use a single third-party logistics provider to handle warehousing of our commercial supply of OMIDRIA in the U.S. and to ship OMIDRIA to our wholesalers. Our third-party logistics provider also performs certain support services on our behalf. Nearly all of our revenues for the fiscal year ended December 31, 2015 were generated from OMIDRIA product sales in the U.S. Three of our major distributors - AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation - together with entities under their common control each accounted for 10% or more of our total revenue in 2015.

Product Candidates and OMS103. We have laboratories in-house for analytical method development, bioanalytical testing, formulation, stability testing and small-scale compounding of laboratory supplies of product candidates. We utilize contract manufacturers to produce sufficient quantities of product candidates for use in preclinical and clinical studies and to store and distribute our product candidates, and we currently do not own or operate manufacturing facilities for our product candidates. We require manufacturers that produce APIs and finished drug products for clinical use to operate in accordance with cGMPs and all other applicable laws and regulations. We anticipate that we will rely on contract manufacturers to develop and manufacture our product candidates 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 have not yet entered into a commercial supply agreement for any of our product candidates, although we intend to do so prior to the applicable product candidate's commercial launch. Given the nature of the manufacturing processes of our product candidates, we anticipate that we will be capable of identifying contract manufacturers to produce these product candidates and of entering into agreements for the commercial supply of these drugs.

In connection with the OMS103 Agreement, we terminated our agreement with Hospira pursuant to which Hospira had agreed to manufacture and supply our commercial requirements of liquid OMS103. The OMS103 Agreement obligates Fagron to meet performance diligence requirements, including to bear all sales and marketing costs for U.S. sales of OMS103; however, Fagron has not performed its performance diligence obligations under the OMS103 Agreement. For a description of the OMS103 Agreement and Fagron's non-performance, see "License and Development Agreements."

License and Development Agreements

OMS103. In June 2015, we entered into the OMS103 Agreement under which Fagron is obligated to manufacture and commercialize OMS103. Pursuant to the OMS103 Agreement, we granted Fagron an exclusive, royalty-free license to the OMS103 intellectual property, manufacturing information and clinical data to produce, on a large-scale registered basis, and commercialize OMS103 in the United States. If OMS103 is commercialized under the terms of the OMS103 Agreement, we would be eligible to receive payments representing a substantial majority share of gross revenue from future OMS103 product sales within the United States, which revenue share will not be less than a minimum per unit amount. Additionally, we would be eligible to receive up to an aggregate total of $10 million in potential payments upon the achievement of specific commercial milestones and as revenue-share enhancement on early sales. The OMS103 Agreement obligates Fagron to produce under Good Manufacturing Practice, or GMP, and to commercialize OMS103 in the U.S. Unless terminated earlier, the OMS103 Agreement will continue until

expiration of the last-to-expire of the patents in the licensed intellectual property or as otherwise provided under the terms of the OMS103 Agreement. Either party may terminate the OMS103 Agreement earlier if the other party materially breaches the OMS103 Agreement and does not cure the breach within a specified notice period or upon the other party's insolvency. Additionally, we may terminate the OMS103 Agreement earlier if Fagron does not meet its performance diligence requirements, in response to a negative action by a regulatory authority, or if Fagron opposes or challenges any of the licensed patents for OMS103.

Fagron has not performed its performance diligence obligations under the OMS103 Agreement, including initiating sales, and we are currently evaluating our options regarding the OMS103 Agreement and our OMS103 program.
MASP Program. Under our exclusive license agreements with the University of Leicester and MRC, we have agreed to pay royalties to each of the University of Leicester and MRC that are a percentage of any proceeds we receive from the licensed MASP-2 technology during the terms of the agreements. Our exclusive license agreement with the University of Leicester, but not our agreement with the MRC, also applies to other MASPs. The continued maintenance of these agreements requires us to undertake development activities. We must pay low single-digit percentage royalties with respect to proceeds that we receive from products incorporating the licensed technology that are used, manufactured, directly sold or directly distributed by us, and we must pay royalties, in the range of a low single-digit percentage to a low double-digit percentage, with respect to proceeds we receive from sublicense royalties or fees that we receive from third parties to which we grant sublicenses to the licensed technology. We did not make any upfront payments for these exclusive licenses nor are there any milestone payments or reversion rights associated with these license agreements. We also agreed to sponsor research of MASP-2 at these institutions at pre-determined rates for maximum terms of approximately three years. We have agreed to expand the scope of research at the University of Leicester to MASP-3 and have continued the sponsorship of research at the University of Leicester on a year-by-year basis. If mutually agreed, we may sponsor additional research related to MASP-2 at MRC, and to MASP-2 and MASP-3 at the University of Leicester. We retain worldwide exclusive licenses from these institutions to develop and commercialize any intellectual property rights developed in the sponsored research. The term of each license agreement ends when there are no longer any pending patent applications, applications in preparation or unexpired issued patents related to any of the intellectual property rights we are licensing under the agreement. Both of these license agreements may be terminated prior to the end of their terms by us for convenience or by one party if the other party (1) breaches any material obligation under the agreement and does not cure such breach after notice and an opportunity to cure or (2) is declared or adjudged to be insolvent, bankrupt or in receivership and materially limited from performing its obligations under the agreement.
In April 2010, we entered into an exclusive license agreement with Helion Biotech ApS, or Helion, pursuant to which we received a royalty-bearing, worldwide exclusive license to all of Helion's intellectual property rights related to MASP-2 antibodies, polypeptides and methods in the field of inhibition of mannan-binding lectin-mediated activation of the complement system for the prevention, treatment or diagnosis of any disease or condition. We are obligated to make remaining development and sales milestone payments to Helion of up to $6.1 million upon the achievement of certain events, such as the filing of an IND with the FDA, initiation of Phase 2 and 3 clinical trials, receipt of marketing approval, and reaching specified sales milestones. We are obligated to pay Helion a low single-digit percentage royalty on net sales of a MASP-2 inhibitor product covered by the patents licensed under the agreement. The term of the agreement continues so long as there is a valid, subsisting and enforceable claim in any patents or patent applications covered by the agreement. The agreement may be terminated sooner by either party following a material breach of the agreement by the other party that has not been cured within 90 days.
OMS824. We have agreed to pay royalties to SMRI based on any net income we receive from sales of a PDE10 product until we have paid a maximum aggregate amount that is a low single-digit multiple of the amount of grant funding that we have received from SMRI. This multiple increases as time elapses from the date we received the grant funding. There are no minimum payment obligations under our agreement with SMRI. Based on the amount of grant funding that we received from SMRI, the maximum amount of royalties payable to SMRI is $12.8 million and payment is required only from any net income, after all related expenses, that we receive from sales of a PDE10 product. The funding agreement and our obligation to pay a royalty to SMRI terminate when we have repaid such amount in the form of royalties.
PPAR . We acquired the patent applications and related intellectual property rights for our PPAR program in February 2009 from Roberto Ciccocioppo, Ph.D. of the Università di Camerino, Italy, pursuant to a patent assignment agreement. In February 2011, we amended the agreement to include all intellectual property rights, including patent applications, related to nutraceuticals that increase PPAR activity. Under the amended agreement, we have agreed to pay Dr. Ciccocioppo a low-single digit percentage royalty on net sales of any products that are covered by any patents that issue from the patent applications that we acquired from him. In addition, if we grant any third parties rights to

manufacture, sell or distribute any such products, we must pay to Dr. Ciccocioppo a percentage of any associated fees we receive from such third parties in the range of low single-digits to low double-digits depending on the stage of development at which such rights are granted. We have also agreed to make total milestone payments of up to $3.8 million to Dr. Ciccocioppo upon the occurrence of certain development events, such as patient enrollment in a Phase 1 clinical trial and receipt of marketing approval of a product candidate 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.

PDE7. Under an agreement with Daiichi Sankyo, we hold an exclusive license to PDE7 inhibitors claimed in certain patents and pending patent applications owned by Daiichi Sankyo for use in the treatment of (1) movement disorders and other specified indications, (2) addiction and compulsive disorders and (3) all other diseases except those related to dermatologic conditions. Under the agreement, we agreed to make milestone payments to Daiichi Sankyo of up to an aggregate total of $33.5 million upon the achievement of certain events in each of these three fields; however, if only one of the three indications is advanced through the milestones, the total milestone payments would be $23.5 million. The milestone payment events include successful completion of preclinical toxicology studies; dosing of human subjects in Phase 1, 2 and 3 clinical trials; receipt of marketing approval of a PDE7 inhibitor product candidate; and reaching specified sales milestones. In addition, Daiichi Sankyo is entitled to receive from us a low single-digit percentage royalty of any net sales of a PDE7 inhibitor licensed under the agreement by us and/or our sublicensee(s) provided that, if the sales are made by a sublicensee, then the amount payable by us to Daiichi Sankyo is capped at an amount equal to a low double-digit percentage of all royalty and specified milestone payments received by us from the sublicensee.

The term of the agreement with Daiichi Sankyo continues so long as there is a valid, subsisting and enforceable claim in any patents covered by the agreement. The agreement may be terminated sooner by us, with or without cause, upon 90 days advance written notice or by either party following a material breach of the agreement by the other party that has not been cured within 90 days or immediately if the other party is insolvent or bankrupt. Daiichi Sankyo also has the right to terminate the agreement if we and our sublicensee(s) cease to conduct all research, development and/or commercialization activities for a PDE7 inhibitor covered by the agreement for a period of six consecutive months, in which case all rights held by us under Daiichi Sankyo's patents will revert to Daiichi Sankyo.

OMS616. On December 14, 2010, we entered into a license agreement with The Regents of the University of California, pursuant to which we received an exclusive license to a series of antifibrinolytic agents claimed in certain patents owned by The Regents of the University of California in exchange for our agreement to make royalty and development milestone payments.

GPCR Platform Funding Agreements with Vulcan Inc. and the Life Sciences Discovery Fund. In October 2010, we entered into funding agreements for our GPCR program with Vulcan and LSDF. We received $20.0 million and $5.0 million, respectively, under the agreements with Vulcan and LSDF. Under these agreements, we have agreed to pay Vulcan and LSDF tiered percentages of the net proceeds, if any, that we derive from the GPCR program. The percentage rates of net proceeds payable to Vulcan and LSDF decrease as the cumulative net proceeds reach specified thresholds, and the blended percentage rate payable to Vulcan and LSDF in the aggregate is in the mid-teens with respect to the first approximately $1.5 billion of cumulative net proceeds that we receive from our GPCR program. If we receive cumulative net proceeds in excess of approximately $1.5 billion, the percentage rate payable to Vulcan and LSDF in the aggregate decreases to one percent. An acquirer of the assets in our GPCR program may be required, and an acquirer of our company would be required, to assume all of our payment and other obligations under our agreements with Vulcan and LSDF.

Under our agreement with Vulcan, we granted Vulcan a security interest in our personal property related to the GPCR program, other than intellectual property, which security interest is junior to any existing or future security interests granted in connection with a financing transaction and which will be released automatically after Vulcan receives $25.0 million under the agreement. We also agreed not to grant any liens on intellectual property related to the GPCR program without Vulcan's consent, subject to specified exceptions. These restrictions could limit our ability to pursue business opportunities involving the GPCR program or reduce the price for which a potential buyer would pay for the GPCR assets. If we default under our agreement with Vulcan, in certain circumstances Vulcan may, subject to the rights of any holders of senior security interests, take control of such pledged assets. If we are liquidated, Vulcan's

right to receive any payments then due under our agreement would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation of our GPCR program assets.

The term of our agreement with Vulcan is 35 years, provided that the term will automatically extend until the cumulative net proceeds that we receive from the GPCR program are approximately $1.5 billion. The term of our agreement with LSDF expires on the six-month anniversary following the last date that we deliver a report related to our incurrence of grant-funded expenses described in the agreement, provided that certain obligations will survive the expiration of the term. The term of our payment obligations to LSDF is the same as that under our agreement with Vulcan.

Antibody Platform. We hold a worldwide exclusive license to patent rights related to our antibody platform from the University of Washington, or UW. Pursuant to the Xori APA, we acquired all of Xori's exclusive rights under a license agreement with the UW to certain patents and patent applications related to our antibody platform owned by the UW in exchange for our agreement to make royalty and development milestone payments to UW.

Competition

Overview. The pharmaceutical industry is highly competitive and characterized by a number of established, large pharmaceutical companies as well as smaller companies like ours. We expect to compete with other pharmaceutical and biotechnology companies, and our competitors may:

- develop and market products that are less expensive, more effective or safer than our future products;
- commercialize competing products before we can launch our products;
- operate larger research and development programs, possess greater manufacturing capabilities or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research 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. Further, our competitors may render our technologies obsolete by advancing their existing technological approaches or developing new or different approaches. If we fail to stay at the forefront of technological change, we may be unable to compete effectively.

OMIDRIA. We are not aware of any products comprised of two or more APIs that directly compete with OMIDRIA, or our PharmacoSurgery product candidates, that are approved for intraoperative delivery in irrigation solutions during surgical procedures; however, OMIDRIA and our PharmacoSurgery product candidates could compete with single API products that are delivered intraoperatively as well as preoperative and postoperative treatments for mydriasis, pain or inflammation. Our primary competition for OMIDRIA could come from surgeons' current practices, which may include use of products obtained from distributors or compounding pharmacies at a relatively low cost. In addition, we anticipate that there are some surgeons who do not use intraoperative mydriatics and may not agree with the value proposition of maintaining pupil dilation and inhibiting miosis during the procedure or with the use of a nonsteroidal anti-inflammatory drug, or NSAID, intraoperatively to reduce inflammation and postoperative pain. Although we are not aware of any companies developing similar combination approaches for maintenance of intraoperative pupil size and postoperative pain reduction, such strategies may develop now that OMIDRIA is marketed in the U.S.

As described above, Par filed an ANDA containing a Paragraph IV Certification seeking approval to market a generic version of OMIDRIA prior to the expiration of the Orange Book Patents. An adverse outcome in our patent infringement lawsuit filed against Par following receipt of Par's Notice Letter regarding the Paragraph IV Certification could, among other things, result in a generic version of OMIDRIA being launched after the expiration of the mandatory three-year clinical data exclusivity for OMIDRIA, which could have a material negative impact on our financial condition and results of operations. In the future, other manufacturers may potentially file ANDAs seeking approval for the sale of generic versions of OMIDRIA before our relevant patents expire, or generic manufacturers may challenge one or more of the patents using U.S. Patent and Trademark Office procedures. For more information regarding the ANDA filed by Par and our patent infringement lawsuit against Par, see Part I, Item 3, "Legal Proceedings."

Product Candidates. Our clinical and preclinical product candidates may face competing products. For example, we are developing PDE10 inhibitors for use in the treatment of Huntington's disease, schizophrenia and other diseases that affect cognition. Other pharmaceutical companies, many with significantly greater resources than we have, are also

developing, or may develop, PDE10 inhibitors for the treatment of Huntington's disease, schizophrenia and other diseases that affect cognition, and these companies may be further along in development. In addition, Soliris® is a complement inhibitor approved for commercial use that will compete with our lead MASP-2 inhibitor OMS721, and/or our MASP-3 inhibitor OMS906, if either is approved for any indication(s) for which Soliris® is also approved. Additionally, The Nordic

Group is currently authorized to market Trasylol® in Europe for patients undergoing coronary artery bypass graft surgery. In September 2011, the marketing authorization for Trasylol® was also reinstated in Canada, with additional safety warnings, for patients undergoing coronary artery bypass graft surgery. Any product candidate that we develop in our Plasmin program for the same indication would directly compete with Trasylol® in any countries in which Trasylol® is authorized to be marketed. Also, we are aware that other companies are attempting to de-orphanize orphan GPCRs. If any of these companies is able to de-orphanize an orphan GPCR before we do, we may be unable to establish an exclusive or commercially valuable intellectual property position around that orphan GPCR.

Intellectual Property

As of March 8, 2016, we owned or held worldwide exclusive licenses to a total of 55 issued patents and 72 pending patent applications in the U.S. and 310 issued patents and 327 pending patent applications in foreign markets directed to therapeutic compositions and methods related to our development programs. For each program, our decision to seek patent protection in specific foreign markets, in addition to the U.S., is based on many factors, including one or more of the following: our available resources, the size of the commercial market, the presence of a potential competitor or a contract manufacturer in the market and whether the legal authorities in the market effectively enforce patent rights.

Our patent portfolio for our PharmacoSurgery technology is directed to locally delivered compositions and treatment methods using agents selected from broad therapeutic classes. These patents and patent applications are directed to combinations of agents, generic and/or proprietary to us or to others, delivered locally and intraoperatively to the site of any medical or surgical procedure. As of March 8, 2016, our patent portfolio included nine U.S. and 50 foreign issued or allowed patents, and 14 U.S. and 72 foreign pending patent applications, directed to our PharmacoSurgery products and development programs. Our issued PharmacoSurgery patents have terms that will expire as late as October 23, 2033 for OMIDRIA, September 24, 2022 for OMS103, and July 16, 2029 for OMS201, and, if currently pending patent applications are issued, as late as November 30, 2035 for OMIDRIA, August 3, 2032 for OMS103, and March 17, 2026 for OMS201.

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 used in ophthalmologic procedures including intraocular procedures (OMIDRIA), arthroscopic procedures (OMS103), and urologic procedures including ureteroscopy (OMS201) as well as covering the specific combinations of agents included in each of these products and product candidates.

- OMIDRIA-Ophthalmology. OMIDRIA is encompassed by our PharmacoSurgery patent portfolio. The relevant patents and patent applications in this portfolio are directed to combinations of agents, generic and/or proprietary to us or to others, drawn from therapeutic classes such as pain and inflammation inhibitory agents, mydriatic agents and agents that reduce intraocular pressure, delivered locally and intraoperatively to the site of ophthalmological procedures, including cataract and lens replacement surgery. As of March 8, 2016, we owned four issued U.S. patents and four pending U.S. patent applications and 31 issued patents and 55 pending patent applications in foreign markets that are directed to OMIDRIA.
- OMS103-Arthroscopy. OMS103 is encompassed by our PharmacoSurgery patent portfolio. The relevant patents and patent applications in this portfolio are directed to combinations of agents, generic and/or proprietary to us or to others, drawn from therapeutic classes such as pain and inflammation inhibitory agents and vasoconstrictive agents, delivered locally and intraoperatively to the site of medical or surgical procedures, including arthroscopy. As of March 8, 2016, we owned three issued U.S. patents, four pending U.S. patent applications, and 12 issued patents and 16 pending patent applications in foreign markets, that are directed to OMS103.
- OMS201-Urology. OMS201 is encompassed by our PharmacoSurgery patent portfolio. The relevant patents and patent applications in this portfolio are directed to combinations of agents, generic and/or proprietary to us or to others, drawn from therapeutic classes such as pain and inflammation inhibitory agents and spasm inhibitory agents, delivered locally and intraoperatively to the site of medical or surgical procedures, including uroendoscopy. As of March 8, 2016, we owned one issued U.S. patent, two pending U.S. patent applications, and an additional seven issued patents and two pending patent applications in foreign markets, that are directed to OMS201.
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MASP-2 Program - OMS721. We hold worldwide exclusive licenses to rights in connection with MASP-2, the antibodies targeting MASP-2 and the therapeutic applications for those antibodies from the University of Leicester, MRC and Helion. As of March 8, 2016, we exclusively controlled 13 issued patents and 22 pending patent applications in the U.S., and 61 issued patents and 87 pending patent applications in foreign markets, related to our MASP-2 program and associated complement targets.

- PDE10 Program - OMS824. As of March 8, 2016, we owned six issued patents and six pending patent application in the U.S., and 12 issued patents and 25 pending patent applications in foreign markets, that are directed to proprietary PDE10 inhibitors.
- PPAR Program - OMS405. As of March 8, 2016, we owned one issued patent and three pending patent applications in the U.S., and 15 issued patents and 25 pending patent applications in foreign markets, directed to our discoveries linking PPAR and addictive disorders.
- PDE7 Program - OMS527. As of March 8, 2016, we owned two issued patents and two pending patent applications in the U.S., and 14 issued patents and 17 pending patent applications in foreign markets directed to our discoveries linking PDE7 to movement disorders, as well as one issued patent and two pending patent applications in the U.S., and three issued patents and 25 pending patent applications in foreign markets directed to the link between PDE7 and addiction and compulsive disorders. Additionally, under a license from Daiichi Sankyo, we exclusively control rights to three issued U.S. patents and 57 issued and five pending patent applications in foreign markets that are directed to proprietary PDE7 inhibitors. For a more detailed description of our agreement with Daiichi Sankyo, see “License and Development Agreements.”
- Plasmin Program - OMS616. We hold worldwide exclusive licenses to a series of antifibrinolytic agents from The Regents of the University of California. As of March 8, 2016, we exclusively controlled three issued patents and two pending patent applications in the U.S. and 22 issued and 12 pending patent applications in foreign markets that are directed to these proprietary agents.
- MASP-3 Program - OMS906. We own and exclusively control under a license from the University of Leicester all rights to methods of treating various disorders and diseases by inhibiting MASP-3. As of March 8, 2016, we exclusively controlled two pending patent applications in the U.S. and 33 pending patent applications in foreign markets that are directed to these therapeutic methods.
- GPR17. As of March 8, 2016, we owned two pending patent applications in the U.S. directed to compounds that functionally interact with GPR17 and their therapeutic applications.
- GPCR Platform. As of March 8, 2016, we owned seven issued patents and 13 pending patent applications in the U.S., and 50 issued patents and seven pending patent applications in foreign markets, which are directed to previously unknown links between specific molecular targets in the brain and a series of CNS disorders, to our cellular redistribution assay and to other research tools that are used in our GPCR program, and to orphan GPCRs and other GPCRs for which we have identified functionally interacting compounds using our cellular redistribution assay.
- Antibody Platform. As of March 8, 2016, we owned and/or held worldwide exclusive license rights from the UW to four issued patents and four pending patent applications in the U.S., and three issued patents and 14 pending patent applications in foreign markets, directed to our antibody platform and antibodies generated using our platform.

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 that 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 products and product candidates and the methods used to manufacture them, as well as on our ability to defend successfully these patents against third-party challenges. Our ability to protect our products and 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 U.S., 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 U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. 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 worldwide manufacturing, marketing and distribution rights for OMIDRIA and each of our product candidates and programs other than OMS103. Some of our products and product candidates and programs are

based on inventions and other intellectual property rights that we acquired through assignments, exclusive licenses or acquisitions.

- PharmacoSurgery Platform. Our scientific co-founders, Gregory A. Demopulos, M.D. and Pamela Pierce Palmer, M.D., Ph.D., conceived the initial invention underlying our PharmacoSurgery platform and transferred all of their related intellectual property rights to us in 1994. Other than their rights as shareholders, our scientific co-founders have not retained any rights to our PharmacoSurgery platform, except that if we file for liquidation under Chapter 7 of the U.S. Bankruptcy Act or voluntarily liquidate or dissolve, other than in connection with a merger, reorganization, consolidation or sale of assets, our scientific co-founders have the right to repurchase the initial PharmacoSurgery intellectual property at the then-current fair market value. Subsequent developments of the PharmacoSurgery intellectual property were assigned to us by Dr. Demopulos, Dr. Palmer and other of our employees and consultants, without restriction.
- PDE10 and PDE7 Programs. We acquired our PDE10 and PDE7 programs and some of our related patents and other intellectual property rights as a result of our acquisition of nura, inc. We hold an exclusive license to certain PDE7 inhibitors claimed in patents and pending patent applications owned by Daiichi Sankyo for use in the treatment of movement, addiction and compulsive disorders as well as other specified indications. For a more detailed description of our agreement with Daiichi Sankyo, see “License and Development Agreements.”
- MASP 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, MRC and Helion. We jointly own and hold worldwide exclusive license rights related to therapeutic applications for inhibiting MASP-3 from the University of Leicester. For more detailed descriptions of these licenses, see “License and Development Agreements.”
- PPAR Program. We acquired the patent applications and related intellectual property rights for our PPAR program in 2009 from Roberto Ciccocioppo, Ph.D., of the Università di Camerino, Italy, pursuant to a patent assignment agreement. For a more detailed description of this agreement, see “License and Development Agreements.”
- Plasmin Program. We hold a worldwide exclusive license to patent rights related to certain antifibrinolytics from The Regents of the University of California. For a more detailed description of this agreement, see “License and Development Agreements.”
- GPCR Platform. We acquired our GPCR program and some of our related patents and other intellectual property rights as a result of our acquisition of nura, inc. In November of 2010 we acquired intellectual property rights related to an assay technology for our GPCR program from Patobios Limited for approximately $10.8 million.
- Antibody Platform. We hold a worldwide exclusive license to patent rights related to our antibody platform from the UW. For a more detailed description of this agreement, see “License and Development Agreements.

Government Regulation

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

In the U.S., our products and product candidates are regulated by the FDA as drugs or biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations and, in the case of biologics, also under the Public Health Service Act. In Europe, our products and product candidates are regulated by the EMA and national medicines regulators under the rules governing medicinal products in the EU as well as national regulations in individual countries. OMIDRIA has received marketing approval from the FDA and from the applicable regulatory authorities in the EU. Our product candidates are in various stages of testing and none of our product candidates, nor OMS103, has received marketing approval from the FDA or the applicable regulatory authorities in the EU.

The steps required before a product may be approved for marketing by the FDA or the applicable regulatory authorities typically include the following:

- formulation development and manufacturing process development;

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- preclinical laboratory and animal testing;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin; and in Europe, a CTA is filed according to the country's local regulations;
- adequate and well-controlled human clinical trials to establish the efficacy and safety of the product for each indication for which approval is sought;
- adequate assessment of drug product stability to determine shelf life/expiry dating;
- in Europe, submission to the EMA or national regulatory authority of a marketing authorization application, or MAA, and in the U.S., submission to the FDA of a New Drug Application, or NDA, in the case of a drug product, or a BLA in the case of a biologic product;
- satisfactory completion of inspections of clinical sites at which clinical trials with the product were carried out and of the manufacturing facility or facilities at which the product is produced to assess compliance with current Good Clinical Practices, or cGCP, and cGMP; and
- FDA review and approval of an NDA or BLA, or review and approval of an MAA by the applicable regulatory authorities in the EU.

Manufacturing. Manufacturing of drug products for use in clinical trials must be conducted according to relevant national guidelines, for example, cGMP. Process and formulation development are undertaken to design suitable routes to manufacture the drug substance and the drug product for administration to animals or humans. Analytical development is undertaken to obtain methods to quantify the potency, purity and stability of the drug substance and drug product as well as to measure the amount of the drug substance and its metabolites in biological fluids, such as the blood.

Preclinical Tests. Preclinical tests include laboratory evaluations and animal studies to assess efficacy, toxicity and pharmacokinetics. The results of the preclinical tests, together with manufacturing information, analytical data, clinical development plan, and other available information are submitted as part of an IND or CTA.

The IND/CTA Process. An IND or CTA 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 that event, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before the clinical hold is lifted and clinical trials can proceed. Similarly, a CTA must be cleared by the local independent ethics committee and competent authority prior to conducting a clinical trial in the European country in which it was submitted. This process can take from two weeks to several months. There can be no assurance that submission of an IND or CTA will result in authorization to commence clinical trials. Once an IND or CTA is in effect, there are certain reporting requirements.

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

- Phase 1 usually involves the initial administration of the investigational product to human subjects, who may or may not have the disease or condition for which the product is being developed, to evaluate the safety, dosage tolerance, pharmacodynamics and, if possible, to gain an early indication of the effectiveness of the product.
- Phase 2 usually involves trials in a limited patient population with the disease or condition for which the product is being developed to evaluate appropriate dosage, to identify possible adverse side effects and safety risks, and to evaluate preliminarily the effectiveness of the product for specific indications.
- Phase 3 clinical trials usually further evaluate and confirm effectiveness and test further for safety by administering the product in its final form in an expanded patient population.

We, our product development partners, Institutional Review Boards or Ethics Committees, the FDA or other regulatory authorities may suspend clinical trials at any time on various grounds, including a belief that the subjects are being exposed to an unacceptable health risk.

The Application Process. If the necessary clinical trials are successfully completed, the results of the preclinical trials and the clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA in the form of an NDA or a BLA, as applicable, and to the EMA or national regulators in the form of an MAA, requesting approval to market the product for a specified indication. In the EU, an MAA

may be submitted to the EMA for review and, if the EMA gives a positive opinion, the European Commission may grant a marketing authorization that is valid across the EU (centralized procedure). Alternatively, an MAA may be submitted to one or more national regulators in the EU according to one of several national or decentralized procedures. The type of submission in Europe depends on various factors and must be cleared by the appropriate authority prior to submission. For most of our product candidates, the centralized procedure will be either mandatory or available as an option.

If the regulatory authority determines that the application is not acceptable, they may refuse to accept the application for filing and review, outlining the deficiencies in the application and specifying additional information needed to file the application. Notwithstanding the submission of any requested additional testing or information, the regulatory authority ultimately may decide that the application does not satisfy the criteria for approval. Before approving an NDA or BLA, or an MAA, the FDA or the EMA, respectively, may inspect the clinical sites at which the Phase 3 study(ies) were conducted to assure that GCPs were followed and may inspect facility(ies) at which the product is manufactured to assure satisfactory compliance with cGMP. After approval, changes to the approved product such as adding new indications, manufacturing changes, or additional labeling claims will require submission of a supplemental application or, in some instances, a new application, for further review and approval. The testing and approval process requires substantial time, effort, and financial resources, and we cannot be sure that any future approval will be granted on a timely basis, if at all.

Some of our drug products may be eligible for submission to the FDA of NDAs 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 in addition to 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 products and product candidates, such as OMIDRIA and OMS103, as fixed-dose combination drugs under its Combination Drug Policy (21 CFR Section 300.50) because they are comprised of two or more active ingredients. In addition to demonstrating that the drug product is safe and effective, the FDA's Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's effectiveness. The EMA has a similar Guideline for fixed-dose combination products. Satisfaction of the U.S. or EU requirements for fixed-dose combination products may involve substantial time, effort, and financial resources, and we cannot be sure that work conducted to satisfy these requirements will be deemed acceptable by the applicable regulatory authority.

Some of our product candidates, such as those from our MASP-2, MASP-3 and Plasmin programs, are considered biologics because they are derived from natural sources as opposed to being chemically synthesized. The added complexity associated with manufacturing biologics may result in additional monitoring of the manufacturing process and product changes.

In addition, we, our suppliers, and our contract manufacturers are required to comply with extensive FDA and EMA requirements both before and after approval. For example, we must establish a pharmacovigilance system and are required to report adverse reactions and production problems, if any, to the regulatory authorities. We must also comply with certain requirements concerning advertising and promotion for our products. The regulatory authorities may impose specific obligations as a condition of the marketing authorization, such as additional safety monitoring, or the conduct of additional clinical trials or post-marketing safety studies. Also, quality control and manufacturing procedures must continue to conform to cGMPs after approval. Accordingly, manufacturers must continue to expend time, money, and effort in all areas of regulatory compliance, including production and quality control to comply with cGMPs. In addition, discovery of problems such as safety issues may result in changes in labeling or restrictions on a product manufacturer or marketing authorization holder, including removal of the product from the market.

Programs for Expedited Review. Section 506(b) of the FDCA provides for the designation of a drug as a fast track product if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a

disease or condition. A program with Fast Track status is afforded greater access to the FDA for the purpose of expediting the product's development, review and potential approval. Many products that receive Fast Track designation are also considered appropriate to receive Priority Review, and their respective applications may be accepted by the FDA as a rolling submission in which portions of an NDA are reviewed before the complete application is submitted. Together, these may reduce time of development and FDA review time. In Europe, products that are considered to be of major public health interest are eligible for accelerated assessment, which shortens the review period substantially. The grant of Fast Track status, Priority Review or accelerated assessment does not alter the standard regulatory requirements for obtaining marketing approval, however.

Orphan Drug Designation. Under the Orphan Drug Act, or ODA, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S. or more than 200,000 individuals in the U.S. for which the cost of developing and making the product available in the U.S. for this type of disease or condition is not likely to be recovered from U.S. sales for that product. The granting of orphan designation does not alter the standard regulatory requirements and process for obtaining marketing approval. If a product that has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the sponsor of the product qualifies for various development incentives specified in the ODA, including tax credits for qualified clinical testing. Furthermore, the product is entitled to an orphan drug exclusivity period, which means the FDA may not grant approval to any other application to market the same drug for the same indication for a period of seven years except in limited circumstances. The EU has a similar Orphan Drug program to that of the U.S., and it is administered through the EMA's Committee for Orphan Medicinal Products, or COMP.

Pediatric Testing and Exclusivity. In the United States, NDAs and BLAs are subject to both mandatory pediatric testing requirements and voluntary pediatric testing incentives in the form of pediatric exclusivity. An additional six months of exclusivity in the U.S. may be granted to a sponsor of an NDA or BLA if the sponsor conducts certain pediatric studies. This process is initiated by the FDA as a written request for pediatric studies to determine if the drug or biologic could have meaningful pediatric health benefits. If the FDA determines that the sponsor has conducted the requested pediatric studies in accordance with the written request, then an additional six months of pediatric exclusivity may attach in the case of a drug to any other regulatory exclusivity or patent protection applicable to the drug, and in the case of a biologic to any other regulatory exclusivity applicable to the biologic. The EU has a similar requirement and incentive for the conduct of pediatric studies according to the pediatric investigation plan, which must be adopted by the EMA before an MAA may be submitted.

Labeling, Marketing, and Promotion. The FDA closely regulates the labeling, marketing and promotion of drugs. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties.

In addition, in the U.S. the research, manufacturing, distribution, sale and promotion of drug products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. Violations of these laws are punishable by prison sentences, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information or impose other special requirements for the sale and marketing of drug products. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, federal and state "transparency laws" require manufacturers to track and report certain payments made to healthcare providers. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Compounding Pharmacies and Registered Outsourcing Facilities. Title I (the Compounding Quality Act) of the DQSA, which was enacted in November 2013, amends the FDCA to establish a distinct category of drug compounders known as "outsourcing facilities." A compounding pharmacy that elects to register with the FDA as an outsourcing facility is exempt from certain FDCA requirements, including the obligation to obtain FDA approval of an NDA, if the facility satisfies conditions set out in the statute. The DQSA also imposes restrictions on the materials that may be compounded at registered outsourcing facilities. Like "traditional" pharmacy compounders, such as those found in hospitals, outsourcing facilities may not compound drugs that are "essentially a copy of one or more approved drugs" or that present "demonstrable difficulties for compounding." The statute also imposes conditions on the compounding of bulk substances. The FDA has identified compounding as an enforcement priority in 2016, but it remains to be seen how the agency will interpret key provisions of the DQSA, such as the prohibition on

compounding drugs that are “essentially a copy of one or more approved drugs,” and to what extent the DQSA gives the agency sufficient authority to regulate compounding activities in violation of the FDCA.

Drug Supply Chain Security Act. Title II (the Drug Supply Chain Security Act), or DSCSA, of the DQSA imposes on manufacturers of certain pharmaceutical products new obligations related to product tracking and tracing, among others, which will be phased in over several years beginning in 2015. Among the requirements of this legislation, manufacturers subject to the DSCSA will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier and keep certain records regarding

the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Covered manufacturers will also be required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under the DSCSA, covered manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Foreign Regulatory Requirements. Outside of the U.S., our ability to conduct clinical trials or market our products will also depend on receiving the requisite authorizations from the appropriate regulatory authorities. The foreign regulatory approval processes include similar requirements and many of the risks associated with the FDA and/or the EMA approval process described above, although the precise requirements may vary from country to country.

Hatch-Waxman Act. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or an approved method of use of the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or a 505(b)(2) application. An ANDA provides for marketing of a drug that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through testing to be bioequivalent to the listed drug. ANDA applicants are generally not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug, other than the requirement for bioequivalence testing. Drugs approved in this way based on a showing of sameness and bioequivalence to the listed drug are considered therapeutically equivalent, and are commonly referred to as "generic equivalents" to the listed drug. These drugs then generally can be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA or 505(b)(2) applicant is required to certify to the FDA concerning any patents listed for the referenced approved drug in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or unenforceable, or will not be infringed by the new drug. A certification that the new drug will not infringe the already approved drug's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV Notice Letter. If the applicant does not challenge the listed patents, the ANDA or 505(b)(2) application will not be approved until all of the listed patents claiming the referenced drug have expired.

If the ANDA or 505(b)(2) applicant has provided a Paragraph IV Notice Letter to the FDA, the applicant must also send notice of the Paragraph IV Notice Letter to the NDA and patent holders once the ANDA or 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV Notice Letter. The filing of a patent infringement lawsuit within 45 days of the receipt of notice of a Paragraph IV Notice Letter automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, modification by a court or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced drug has expired. The U.S. Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act," provides a period of five years following approval of a drug containing no previously approved active moiety, during which ANDAs for generic versions of those drugs and 505(b)(2) applications referencing those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original drug approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials, other than bioavailability studies, conducted by or for the sponsor, during which FDA cannot grant effective approval of an ANDA or 505(b)(2) application based on that listed drug.

As described above, Par has sent a Paragraph IV Notice Letter stating that it has filed an ANDA containing a Paragraph IV Certification under the Hatch-Waxman Act seeking approval from the FDA to market a generic version of OMIDRIA prior to the expiration of the Orange Book Patents. Following receipt of Par's Notice Letter regarding the Paragraph IV Certification, in September 2015, we filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par. For more information regarding the ANDA filed by Par and our patent infringement lawsuit against Par, see Part I, Item 3, "Legal Proceedings."

Healthcare compliance laws. In the U.S., commercialization of Omidria and our product candidates, if approved, is subject to regulation and enforcement under a number of federal and state healthcare compliance laws administered and enforced by agencies other than the FDA. These include the following:

- the federal Anti-Kickback Law, which prohibits offering or paying anything of value to a person or entity to induce the use of a good or service covered by a federal health care program such as Medicare or Medicaid;
- the federal False Claims Act, which prohibits presenting or causing to be presented a false claim for payment by a federal health care program, and which has been interpreted to include claims caused by improper drug-manufacturer product promotion or the payment of kickbacks;
- a variety of governmental pricing, price reporting, and rebate requirements, including those under Medicaid and the Veterans Health Care Act; and
- the so-called Sunshine Act and related provisions of the Affordable Care Act, which require that we report to the federal government information on financial payments that we make to physicians and certain healthcare institutions and also on drug samples that we distribute.

In addition to these federal law requirements, there are related state law requirements. Also, if we receive protected patient health information, we may be subject to federal or state privacy laws.

Similar requirements apply to our ex-U.S. operations. U.S. laws such as the Foreign Corrupt Practices Act prohibit the offering or payment of bribes or inducements to foreign public officials, including potentially physicians or other medical professionals who are employees of public health care entities. In addition, many countries have their own laws similar to the healthcare compliance laws that exist in the U.S.

Pharmaceutical Pricing and Reimbursement

Overview. In both U.S. and foreign markets, our ability to commercialize our products and product candidates successfully, and to attract commercialization partners for our products and product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party or private payers including, in the U.S., managed care organizations and private health insurers as well as governmental payers such as the Medicare and Medicaid programs. Reimbursement by a third-party payer may depend on a number of factors, including the payer'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.

Reimbursement by government payers may depend on the same or similar factors as reimbursement by private third-party payers and also depends on complex regulations that may change with annual or more frequent rulemaking and other legislative activities.

Third-party private and governmental payers are increasingly challenging the prices charged for medicines and examining their cost effectiveness in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products or product candidates. Even with the availability of such studies, third-party private and/or governmental payers may not provide coverage and reimbursement for our products or product candidates, in whole or in part.

United States. Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost-containment measures, including those listed above, or other healthcare system reforms that are adopted could have a material adverse effect on our business prospects.

In October 2014 we were granted transitional pass-through reimbursement status by CMS for OMIDRIA, which became effective January 1, 2015. Pass-through status allows for separate payment for OMIDRIA under Medicare Part B

as opposed to having OMIDRIA be included as part of the existing packaged payment for cataract surgery when performed in hospital outpatient departments and ASCs. We expect pass-through status to remain in effect until January 1, 2018. When the pass-through status was granted, CMS set the Medicare reimbursement rate for OMIDRIA under Medicare Part B at the product's wholesale acquisition cost, or WAC, of $465 plus six percent (6%) per single-use vial for the second and third quarters of 2015 after which the rate is based on ASP plus six percent (6%). If, following the termination of pass-through status for OMIDRIA on December 31, 2017, the drug is packaged into the surgical facility payment, we may need to adjust our pricing accordingly and our revenue could be lower than if separate payment had continued. In addition, reimbursement from private payers may, or may not, reference our CMS reimbursement status in their coverage and payment decisions. Other payers often follow, but are not required to follow, the reimbursement methodology adopted by CMS.

Europe. Governments in the various member states of the EU influence or control the price of medicinal products in their countries through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials or pharmacoeconomic studies that assess the cost-effectiveness of a product candidate relative to currently available therapies or relative to a specified standard. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

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 programmatic 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 on 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 $48.4 million, $47.9 million and $36.3 million in 2015, 2014 and 2013, respectively.

Employees

As of February 29, 2016, we had 162 full-time employees, 82 of whom are in research and development, 52 of whom are in sales and marketing and 28 of whom are in finance, legal, business development and administration. Our full-time employees include six with M.D.s and 25 with Ph.D.s., of whom five and 25, respectively, are in research and development. None of our employees is represented by a labor union, and we consider our employee relations to be good.

Executive Officers and Significant Employees

The following table provides information regarding our executive officers and significant employees as of March 15, 2016:

Name	Age	Position(s)
Executive Officers:		
Gregory A. Demopulos, M.D.	57	President, Chief Executive Officer and Chairman of the Board of Directors
Michael A. Jacobsen	58	Vice President, Finance, Chief Accounting Officer and Treasurer
Marcia S. Kelbon, J.D., M.S.	56	Vice President, Patent, General Counsel and Secretary
Significant Employees:		
Christopher S. Bral, Ph.D.	50	Vice President, Nonclinical Development
Timothy M. Duffy	55	Vice President, Business Development
Kenneth M. Ferguson, Ph.D.	60	Vice President, Development and Chief Development Officer
George A. Gaitanaris, M.D., Ph.D.	59	Vice President, Science and Chief Scientific Officer
William J. Lambert, Ph.D.	57	Vice President, Chemistry, Manufacturing and Controls
Catherine A. Melfi, Ph.D.	57	Vice President, Regulatory Affairs and Quality Systems
Patricia Sandler	47	Vice President, Sales and Marketing
J. Steven Whitaker, M.D., J.D.	60	Vice President, Clinical Development and Chief Medical Officer

Gregory A. Demopulos, M.D. founded our company and has served as our president, chief executive officer and chairman of the board of directors since June 1994. In an interim capacity, he also served as our chief financial officer and treasurer from January 2009 to October 2013 and as our chief medical officer from June 1994 to March 2010. Prior to founding Omeros, Dr. Demopulos completed his residency in orthopedic surgery at Stanford University and his fellowship training in hand and microvascular surgery at Duke University. Dr. Demopulos currently serves on the board of trustees of the Smead Funds Trust, an open-end mutual fund company registered under the Investment Company Act of 1940, and on the board of directors of Onconome, Inc., a privately held company developing biomarkers for early cancer detection. His non-profit service includes the Seattle Community Development Round Table and the Northwest NeuroNeighborhood board of directors. Dr. Demopulos received his M.D. from the Stanford University School of Medicine and his B.S. from Stanford University. Dr. Demopulos is the brother of Peter A. Demopulos, M.D., a member of our board of directors.

Michael A. Jacobsen joined Omeros in September 2013 and has served as our vice president, finance, chief accounting officer and treasurer since October 2013. Prior to joining Omeros, Mr. Jacobsen served as vice president of finance of Sarepta Therapeutics, Inc. from September 2011 to May 2013 and as its chief accounting officer from September 2011 to December 2012. From April 2007 to August 2011, Mr. Jacobsen was vice president and chief accounting officer at ZymoGenetics, Inc. Prior to his service with ZymoGenetics, Mr. Jacobsen held various roles at ICOS Corporation, including senior director of finance and corporate controller. From April 1995 to October 2001, Mr. Jacobsen held vice president of finance or chief financial officer roles at three companies in the software, computer hardware and internet retailing industries, two of which were publicly traded. Mr. Jacobsen is a certified public accountant and received his bachelor's degree in accounting from Idaho State University.

Marcia S. Kelbon, J.D., M.S. has served as our vice president, patent and general counsel since October 2001 and as our secretary since September 2007. Prior to joining Omeros, 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.

Christopher S. Bral, Ph.D. joined Omeros as our vice president, nonclinical development in October 2015. From April 2014 to October 2015, Dr. Bral was the executive director, toxicology at Arrowhead Research Corporation. From June 2008 to April 2014, Dr. Bral served as director, drug safety evaluation at Vertex Pharmaceuticals. Prior to Vertex, Dr. Bral held various pre-clinical drug safety positions of increasing responsibility at Schering-Plough Research Institute including associate director, drug safety evaluation. Dr. Bral received his Ph.D. in biochemistry and biophysics from Texas A&M University and his B.S. in chemistry from John Carroll University, and has been board-certified in toxicology through the American Board of Toxicology since 2000.

Timothy M. Duffy has served as our vice president, business development since March 2010. From November 2008 to March 2010, Mr. Duffy served as the managing director of Pacific Crest Ventures, a life science consulting firm that he founded. From June 2004 through September 2008, Mr. Duffy served at MDRNA, Inc. (formerly Nastech Pharmaceutical Company, Inc.), a biotechnology company. At MDRNA, he held roles of increasing responsibility in marketing and business development, most recently as the chief business officer. Prior to MDRNA, Mr. Duffy served as vice president, business development at Prometheus Laboratories, Inc., a specialty pharmaceutical company, and as a customer marketing manager at The Procter & Gamble Company. Mr. Duffy received his B.S. from Loras College.
Kenneth M. Ferguson, Ph.D. has served as our vice president, development since November 2010 and as our chief development officer since October 2012. From August 2008 to November 2010, Dr. Ferguson served in various positions, including president, chief executive officer and executive director as well as a consultant, for VacTX International Inc., a biotechnology company. From 1990 to 2007, Dr. Ferguson served at ICOS Corporation. Prior to its acquisition in 2007 by Eli Lilly and Company, Dr. Ferguson served at ICOS as vice president, therapeutic development. He also served as chief operating officer, chief scientific officer and a member of the board of managers of Lilly ICOS LLC, the joint venture of Eli Lilly and ICOS that developed and marketed Cialis®. Following the acquisition of ICOS by Eli Lilly, he served as president of ICOS from January 2007 to December 2007, managing its integration into Eli Lilly. Before joining ICOS, Dr. Ferguson worked for Cold Spring Harbor Laboratory. He holds a Ph.D. in pharmacology from the University of Texas Health Science Center and a B.S. in biological sciences from Cornell University.
George A. Gaitanaris, M.D., Ph.D. has served as our vice president, science since August 2006 and as our chief scientific officer since January 2012. From August 2003 to our acquisition of nura, inc. in August 2006, Dr. Gaitanaris served as the chief scientific officer of nura, a company that he co-founded and that developed treatments for central nervous system disorders. From 2000 to 2003, Dr. Gaitanaris served as president and chief scientific officer of Primal, Inc., a biotechnology company that was acquired by nura in 2003. Prior to co-founding Primal, Dr. Gaitanaris served as staff scientist at the National Cancer Institute. Dr. Gaitanaris received his Ph.D. in cellular, molecular and biophysical studies and his M.Ph. and M.A. from Columbia University and his M.D. from the Aristotelian University of Greece.
William J. Lambert, Ph.D. joined Omeros as our vice president, chemistry, manufacturing and controls in January 2015. From October 2011 to January 2015, Dr. Lambert headed the Innovative Drug Delivery Group of MedImmune, the global biologics research and development arm of AstraZeneca. From January 2006 to September 2011, Dr. Lambert served as senior vice president of pharmaceutical development at Pacira Pharmaceuticals. Prior to Pacira, Dr. Lambert directed drug delivery, product development and cGMP clinical supply groups at Eisai Inc. He has also held various pharmaceutical research positions at Pfizer Inc. and the Upjohn Company. Dr. Lambert received his Ph.D. in Pharmaceutics from the University of Utah and his B.S. in Pharmacy from the University of Rhode Island.
Catherine A. Melfi, Ph.D. has served as our vice president, regulatory affairs and quality systems since October 2012. Dr. Melfi previously served from January 1996 to October 2012 at Eli Lilly and Company, where she held technical and leadership roles of increasing scope and responsibility, including as senior director and scientific director in Global Health Outcomes and Regulatory Affairs, respectively. Prior to joining Eli Lilly, Dr. Melfi held various faculty and research positions at Indiana University, including appointments in its Economics Department, in the School of Public and Environmental Affairs, and in the Indiana University School of Medicine. Dr. Melfi received her Ph.D. in Economics from the University of North Carolina - Chapel Hill and B.S. in Economics from John Carroll University.
Patricia Sandler joined Omeros in May 2014 as our national sales director and has served as our vice president, sales and marketing since November 2014. From October 2007 through September 2013, Ms. Sandler served in sales and marketing roles at Sunovion Pharmaceuticals, Inc., including leading a national allergy/asthma sales team from December 2010 to September 2013, managing the Lunesta brand as executive director for central nervous system product marketing from June 2009 to December 2010 and serving as director of respiratory marketing from October 2007 to June 2009. From July 1998 to October 2007, Ms. Sandler served in marketing and sales roles at Johnson & Johnson including as product director of gastroenterology marketing. Prior to Johnson & Johnson, she held various sales positions at large pharmaceutical companies including SmithKline Beecham Pharmaceuticals and Pfizer Inc. Ms. Sandler received her B.S. in business administration from Bloomsburg University of Pennsylvania.

J. Steven Whitaker, M.D., J.D. has served as our vice president, clinical development and chief medical officer since March 2010. From May 2008 to March 2010, Dr. Whitaker served as the chief medical officer, vice president of clinical development at Allon Therapeutics, Inc., a biotechnology company focused on developing drugs for neurodegenerative diseases. From August 2007 to May 2008, he served as a medical consultant to Accelerator Corporation, a biotechnology-company investor and incubator. From May 1994 to May 2007, Dr. Whitaker served at ICOS Corporation, which was acquired by Eli Lilly and Company in 2007. At ICOS, he held roles of increasing responsibility in clinical research and medical affairs, most recently as divisional vice president, clinical research as well as medical director of the Cialis® global

product team. Dr. Whitaker received his M.D. from the Indiana University School of Medicine, his J.D. from the University of Washington and his B.S. from Butler University.

Corporate Information

We were incorporated in 1994 as a Washington corporation. Our principal executive offices are located at 201 Elliott Avenue West, Seattle, Washington, 98119, and our telephone number is (206) 676-5000. Our website address is www.omeros.com. We make available, free of charge through our investor relations website at investor.omeros.com, our annual report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, including exhibits to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our websites and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. In addition, the public may read and copy any materials we file or furnish with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 or may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Moreover, the SEC maintains a website that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with them at www.sec.gov.

ITEM 1A. RISK FACTORS

The risks and uncertainties described below may have a material adverse effect on our business, prospects, financial condition or operating results. In addition, we may be adversely affected by risks that we currently deem immaterial or by other risks that are not currently known to us. You should carefully consider these risks before making an investment decision. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this Annual Report on Form 10-K.

Risks Related to Our Products, Programs and Operations

Our ability to achieve profitability is dependent on the commercial success of OMIDRIA, for which the broad U.S. launch occurred in April 2015. To the extent OMIDRIA is not successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

OMIDRIA is our only product that has been approved by the FDA for commercial sale in the U.S. and broad-based product sales began in April 2015. For the three and twelve months ended December 31, 2015, we recorded net sales of OMIDRIA of $6.7 million and $13.3 million, respectively. We have not generated revenue from sales of OMIDRIA to date that are sufficient to fund fully our operations and cannot provide assurance that we will generate sufficient revenue from OMIDRIA in the future to fund fully our operations. We will need to generate substantially more product revenue from OMIDRIA to achieve and sustain profitability. Our ability to generate significant revenue from OMIDRIA product sales depends on our ability to achieve increased market acceptance of, and to otherwise market and sell effectively, OMIDRIA, which may not occur for a number of reasons, including:

- a lack of acceptance by physicians, patients, government and private payers and other members of the medical community;
- our limited experience in marketing, selling and distributing OMIDRIA or any other product;
- our limited experience managing third-party commercial manufacturing of OMIDRIA or any other product as well as our limited experience managing and maintaining a commercial sales organization;
- pricing, reimbursement and coverage policies of government and private payers such as Medicare, Medicaid, the Department of Veterans Affairs, or VA, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- the availability, relative price and efficacy of the product as compared to alternative treatment options or branded, compounded or generic competing products;
- an unknown safety risk;
- the failure to enter into and maintain acceptable partnering arrangements for marketing and distribution of OMIDRIA outside of the U.S.;
- changed or increased regulatory restrictions in the U.S., EU and other foreign territories; and

- a lack of adequate financial or other resources.

Our operating results are unpredictable and may fluctuate.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- the level and timing of commercial sales of OMIDRIA as well as our product candidates, if and when approved or commercialized;
- the extent of coverage and reimbursement for OMIDRIA, including following the expiration of pass-through reimbursement effective January 1, 2018, and the amount of OMIDRIA chargebacks, rebates and product returns;
- the extent of any payments received from collaboration arrangements and development funding as well as the achievement of development and clinical milestones under collaboration and license agreements that we may enter into from time to time and that may vary significantly from quarter to quarter; and
- the timing, cost and level of investment in our research and development activities as well as expenditures we will or may incur to acquire or develop additional technologies, products and product candidates.

In addition, the number of procedures in which OMIDRIA or any of our product candidates, if commercialized, would be used may be significantly less than the total number of such procedures performed or total possible market size. These and other factors, including our limited history of product sales, may make it difficult for us to forecast and provide accurate guidance (including updates to prior guidance) related to our expected financial performance. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

We have incurred cumulative operating losses since inception. If we are unable to raise additional capital when needed, our commercial operations may be limited and we may be unable to complete the development and commercialization of our product candidates or to continue our other preclinical development programs.

Our operations have consumed substantial amounts of cash since our incorporation and, as of December 31, 2015, we had an accumulated deficit of approximately $403 million. We expect to continue to spend substantial amounts to:

- continue OMIDRIA sales and marketing;
- continue research and development in our programs;
- make principal and interest payments under the Oxford/EWB Loan Agreement;
- initiate and conduct clinical trials for our programs and product candidates; and
- commercialize and launch product candidates for which we may receive regulatory approval.

We expect to continue to incur additional losses until such time as we generate significant revenue from the sale of OMIDRIA, other commercial products and/or significant partnering revenues. We are unable to predict the extent of any future losses and cannot provide assurance that we will generate sufficient revenue from OMIDRIA in the future to fund fully our operations. To date we have not generated revenue from sales of OMIDRIA that is sufficient to fund fully our operations. If we are unable to generate sufficient revenue from the sale of OMIDRIA, other commercialized products and/or partnering arrangements, we may never become and remain profitable and will be required to raise additional capital to continue to fund our operations. We cannot be certain that additional capital will be available to us on acceptable terms, if at all, when required. Adverse developments to our financial condition or business, as well as disruptions in the global equity and credit markets, may limit our ability to access capital. If we do not raise additional capital when needed through one or more funding avenues, such as corporate partnering or debt or equity financings, 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 preclinical programs or other research and development initiatives. In addition, we may be required to seek collaborators for one or more of our current or future products at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might be available or to relinquish or license on unfavorable terms our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves. We also may have insufficient funds or otherwise be unable to advance our preclinical programs, such as potential new drug targets developed from our GPCR program, to a point where they can generate revenue through partnerships, collaborations or other arrangements. Any of these actions could limit the amount of revenue we are able to generate and harm our business and prospects.

Our independent registered public accounting firm has indicated that our financial condition raises substantial doubt as to our ability to continue as a going concern.

Our financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. However, our independent registered public accounting firm has included in its audit opinion for the year ended December 31, 2015 a statement that there is substantial doubt as to our ability to continue as a going concern as a result of our recurring losses and

financial condition on December 31, 2015. Our ability to continue as a going concern will require us to generate positive cash flow from operations, obtain additional financing, enter into strategic alliances and/or sell assets. The reaction of investors to the inclusion of a going concern statement by our auditors, our current lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into strategic alliances and/or make our scheduled debt payments on a timely basis or at all. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

If OMIDRIA or any other product that we develop and commercialize does not receive adequate reimbursement from governments or private payers, or if we do not establish and maintain market-acceptable pricing for OMIDRIA or those commercialized products, our prospects for revenue and profitability could suffer.

Our future revenues and profitability will depend heavily on the pricing, availability and duration of adequate reimbursement for the use of products that we or our third-party business partners commercialize, including OMIDRIA, from government, private and other third-party payers, both in the U.S. and in other countries. OMIDRIA or any other product that we bring to market may not be considered cost-effective and/or the amount reimbursed for any product may be insufficient to allow us to sell the product profitably. Obtaining reimbursement approval for any product from each government or third-party payer can be a time-consuming and costly process that may require the build-out of a sufficient staff or the engagement of third parties and could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our approved products to each payer. We can provide no assurances at this time regarding the cost-effectiveness of OMIDRIA, OMS103 or any of our product candidates. Further, we can provide no assurance that the amounts, if any, reimbursed to surgical facilities for utilization of any of our surgery-related products, including OMIDRIA, any of our product candidates or OMS103, or to surgeons for the administration and delivery of these products or product candidates will be considered adequate to justify the use of these products or product candidates. In addition, obtaining acceptable coverage and reimbursement from one payer does not guarantee that we will obtain similar acceptable coverage or reimbursement from another payer.

There may be significant delays in obtaining reimbursement for newly approved products, and we may not be able to provide data sufficient to be granted reimbursement. Even when a payer determines that a product is eligible for reimbursement, coverage may be limited to the uses of a product that are either approved by the FDA (or, in other countries, the relevant country's regulatory agency) and/or appear in a recognized drug compendium, and other conditions may apply. Moreover, eligibility for coverage does not mean that any product will be reimbursed at a rate that allows us to make a profit in all cases or at a rate that covers our costs, including research, development, manufacturing, sales and distribution. Increasingly, government and private third-party payers that reimburse for healthcare services and products are requiring that companies provide them with predetermined discounts from list prices and challenging the prices charged for medical products, which could adversely impact the pricing of our products. Pricing may also be adversely affected by changes in the terms, scope and/or complexity of government pricing requirements. Even if we receive reimbursement for a product, the initial rate or method at which the product will be reimbursed could become unfavorable to us at the time reimbursement is initiated or in the future or may be of a limited duration. After the expiration of pass-through reimbursement status for OMIDRIA effective January 1, 2018, we may not be able to maintain or obtain adequate reimbursement for OMIDRIA.

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 EU, our products may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time and expenditure of resources after the receipt of marketing approval for a product. We provide no assurances that the price of any product in one or more of these countries or regions will allow us to make a profit or cover our costs, including research, development, manufacturing, sales and distribution, and as a result we may decide to delay, potentially indefinitely, initiating sales in the particular country or region.

If the reimbursement or pricing that we are able to obtain and maintain for any product that we develop and commercialize, including OMIDRIA, is inadequate in light of our development and other costs, is significantly delayed or subject to overly restrictive conditions, or is denied by one or more payers, there could be a material

adverse effect on our business, financial condition, results of operations and growth prospects.

We are subject to extensive government regulation and the failure to comply with these regulations may have a material adverse effect on our operations and business.

Both before and after approval of any product, we and our suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the U.S. and other countries, covering, among other things, testing, manufacturing, quality control, clinical trials, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable

requirements could result in one or more of the following actions: warning letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties; adverse publicity; and disruptions to our business. Further, government investigations into potential violations of these laws would require us to expend considerable resources and face adverse publicity and the potential disruption of our business even if we are ultimately found not to have committed a violation.

Obtaining FDA approval of our product candidates 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 any of our product candidates 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 or additional work related to chemistry, manufacturing and controls. In addition, we, the FDA or an independent Institutional Review Board or Ethics Committee may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are or would be exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials. If we are required to conduct additional trials or to conduct other testing of our product candidates beyond that which we currently contemplate for regulatory approval, if we are unable to complete successfully 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 face substantial additional expenses, be delayed in obtaining marketing approval for our product candidates or may never obtain marketing approval.

We are also required to comply with extensive governmental regulatory requirements after a product has received marketing authorization. Governing regulatory authorities may require post-marketing studies that may negatively impact the commercial viability of a product. Once on the market, a product may become associated with previously undetected adverse effects and/or may develop manufacturing difficulties. As a result of any of these or other problems, a product's regulatory approval could be withdrawn, which could harm our business and operating results. In addition, we must establish and maintain an effective healthcare compliance program in order to comply with U.S. and other laws applicable to marketed drug products. Implementing an effective compliance program requires the expenditure of significant time and resources. If we are found to be in violation of any of these laws, we may be subject to significant penalties, including civil or criminal penalties, damages and fines as well as exclusion from government healthcare programs.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.

We intend to have OMIDRIA and our product candidates, if approved, marketed outside the U.S. In order to market our products in non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The regulatory approval procedure varies among countries and can involve additional testing and data review. The requirements governing marketing authorization, the conduct of clinical trials, pricing and reimbursement vary from country to country. Approval by the FDA or EC does not ensure approval by regulatory agencies in other jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. The time required to obtain regulatory approval outside the U.S. and EU may differ from that required to obtain FDA or EMA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these "Risk Factors" and we may not obtain foreign regulatory approvals on a timely basis, or at all.

We currently depend on a third party for the commercialization of OMS103 and we cannot guarantee that such commercialization will occur or be successful.

In June 2015 we entered into the OMS103 Agreement pursuant to which we granted Fagron an exclusive, royalty-free license to the OMS103 intellectual property, manufacturing information and clinical data to manufacture and commercialize OMS103 in the U.S. in exchange for potential future payments based on product revenue and achievement of commercial milestones. As a result of entering into the OMS103 Agreement, we discontinued our OMS103 clinical development program and are dependent on Fagron to commercialize OMS103 in the U.S. We cannot control whether Fagron will fulfill its obligations under the OMS103 Agreement or whether the

commercialization of OMS103 will be successful. Fagron has not met the diligence milestones in the OMS103 Agreement, including initiating sales of OMS103, and we are currently evaluating our options with respect to the OMS103 Agreement and the OMS103 program. If we elect to pursue arbitration with Fagron, and/or the OMS103 Agreement is terminated, we can provide no assurances that we will be able to enter into another licensing agreement or have sufficient resources to restart clinical development and conduct any clinical trials if desired. Any of the above risks, if realized, could adversely affect our results of operations.

Under Section 503B of the FDCA, registered outsourcing facilities are required to manufacture under GMP and are subject to FDA inspections and audits. They also are not allowed to manufacture a product that is essentially a copy of one or more FDA-approved drugs. If a licensed registered outsourcing facility such as Fagron is prohibited from commercializing or

from continuing commercial sales of OMS103 following initial commercialization because of violations of any FDA regulations or any other reason, our ability to generate revenue from royalty payments from the licensed registered outsourcing facility and achieve profitability will be adversely affected and the market price of our common stock could decline.

We have no internal capacity to manufacture clinical or commercial supplies of OMIDRIA or our product candidates and intend to rely solely on third-party manufacturers. If the contract manufacturers that we rely on experience difficulties manufacturing OMIDRIA or our product candidates or fail FDA or other regulatory inspections, our clinical trials, regulatory submissions and ability to sell OMIDRIA or any other commercialized product and generate revenue may be significantly limited or delayed.

We rely and intend to continue to rely on third party manufacturers to produce commercial quantities of OMIDRIA and clinical drug supplies of our product candidates that are needed for clinical trials. We cannot provide any assurance that we will be able to enter into or maintain these types of arrangements on commercially reasonable terms, or at all. If we or the manufacturer were to terminate one of these arrangements early, or the manufacturer was unable to supply product quantities sufficient to meet our requirements, we would be required to transfer the manufacturing to an approved alternative facility and/or establish additional manufacturing and supply arrangements. We may also need to establish additional or replacement manufacturers, potentially with little or no notice, in the event that one of our manufacturers fails to comply with FDA and/or other pharmaceutical manufacturing regulatory requirements. 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 may create a shortage of the product. Such alternate supply arrangements may not be available on commercially reasonable terms, or at all. Additionally, if we are unable to engage multiple suppliers to manufacture our products, we may have inadequate supply to meet the demand of our product.

Our contract manufacturers may encounter difficulties with formulation and manufacturing processes that could result in delays in clinical trials and/or regulatory submissions or that could impact adversely the commercialization of our products or product candidates, as well as in the initiation of enforcement actions by the FDA and other regulatory authorities. These difficulties also could result in the recall or withdrawal of a product from the market or a failure to have adequate supplies to meet market demand. If the safety of OMIDRIA or any product candidate supplied by contract manufacturers is compromised due to one or more of those contract manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to maintain regulatory approval of OMIDRIA, to continue sales and marketing of OMIDRIA or to obtain and maintain regulatory approval for one or more of our product candidates, which would harm our business and prospects significantly.

In addition, any product candidate from our MASP-2, MASP-3 or Plasmin programs could be a biologic drug product, and we do not have the internal capability to produce biologics for use in clinical trials or on a commercial scale. There are only a limited number of manufacturers of biologic drug products and we cannot be certain that we can enter into supply agreements with them on commercially reasonable terms, if at all. Any significant delays in the manufacture of clinical or commercial supplies could materially harm our business, financial condition, results of operations and prospects.

Manufacturing under our existing OMIDRIA manufacturing agreement with Patheon, which is for a specific facility, ceased at the end of 2015. Validation of the manufacturing process for OMIDRIA under our Hospira supply agreement has not been completed. We do not expect that any OMIDRIA manufacturing facility will be approved for production before 2017. We anticipated this transition and increased production of OMIDRIA prior to the break in manufacturing, and believe that we will have sufficient supply to meet product needs until OMIDRIA product production is recommenced. However, we can provide no assurances if or when the Hospira manufacturing facility or a second manufacturing facility for OMIDRIA will be in production or whether we can meet market demand for OMIDRIA if demand is greater than we anticipate. Additionally, the damage to or destruction of OMIDRIA inventory, including inventory warehoused at our third-party logistics provider, could also adversely affect our ability to meet market demand. We have obtained insurance coverage for the replacement cost of damaged or destroyed OMIDRIA inventory but such coverage would not compensate us for any resulting loss of sales revenue or a reduction in gross margin.

Ingredients, excipients and other materials necessary to manufacture OMIDRIA or our product candidates may not be available on commercially reasonable terms, or at all, which may adversely affect the development and commercialization of OMIDRIA or those product candidates.

We and our third-party manufacturers must obtain from third-party suppliers the active pharmaceutical ingredients, excipients and primary and secondary packaging materials necessary for our contract manufacturers to produce OMIDRIA and our PharmacoSurgery product candidates for our clinical trials and, to the extent approved or commercialized, for commercial distribution. Although we have entered or intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of active pharmaceutical ingredients, excipients and materials for OMIDRIA and our PharmacoSurgery product candidates, we have not yet entered into agreements for the supply of all such ingredients, excipients

or materials, and we may be unable to secure all such supply agreements or guarantees on commercially reasonable terms, if at all. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients, excipients or materials in a timely manner or in the quantities required. If we or our third-party manufacturers are unable to obtain the quantities of these ingredients, excipients or materials that are necessary for the manufacture of commercial supplies of OMIDRIA, our ability to generate revenue from the sale of OMIDRIA would be materially and adversely affected. Further, if we or our third-party manufacturers are unable to obtain active pharmaceutical ingredients, excipients and materials as necessary for our clinical trials or for the manufacture of commercial supplies of our product candidates, if approved, potential regulatory approval or commercialization would be delayed, which would materially and adversely affect our ability to generate revenue from the sale of our product candidates.

If our clinical trials are delayed, suspended or terminated, we may be unable to develop our product candidates on a timely basis, which would adversely affect our ability to obtain regulatory approvals, increase our development costs and delay or prevent commercialization of approved products.

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

- discussions with the FDA, the EMA or other foreign authorities regarding the scope or design of our clinical trials;
- delays or the inability to obtain required approvals from Institutional Review Boards, Ethics Committees or other responsible entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials for any reason including disease severity, trial protocol design, study eligibility criteria, patient population size (e.g., for orphan diseases or for some pediatric indications), proximity and/or availability of clinical trial sites for prospective patients, availability of competing therapies and clinical trials, regional differences in diagnosis and treatment, perceived risks and benefits of the product or product candidate, physician patient referral practices or the ability to monitor patients adequately before and after treatment;
- lower than anticipated retention rates of patients in clinical trials;
- the need to repeat or conduct additional clinical trials as a result of inconclusive or negative results, failure to replicate positive early clinical data in subsequent clinical trials, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol, an unacceptable study design or other problems;
- adverse findings in clinical or nonclinical studies related to the safety of our product candidates in humans;
- an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval;
- an unfavorable inspection or review by the FDA or other regulatory authority of a clinical trial site or records of any clinical investigation;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials;
- the suspension by a regulatory agency of a trial put on a clinical hold; and
- the amendment of clinical trial protocols to reflect changes in regulatory requirements and guidance or other reasons as well as subsequent re-examination of amendments of clinical trial protocols by Institutional Review Boards or Ethics Committees.

In addition, a clinical trial or development program may be suspended or terminated by us, the FDA or other regulatory authorities, or Institutional Review Boards or Ethics Committees due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- the failure to remove a clinical hold in a timely manner (which we cannot predict with certainty), if at all;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial or development program, 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.

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. 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. Any delays in completing our clinical trials could increase our development costs, could slow down our product development and regulatory submission process, could delay our receipt of product revenue and could make it difficult to raise additional capital. 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, potentially harming our business.

Because we have a number of product candidates and development programs, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications for which there is a greater likelihood of obtaining regulatory approval and that may be more profitable, if approved.

We do not have unlimited resources and must focus on the product candidates and clinical and preclinical development programs that we believe are the most promising. As a result, we may forego or delay the pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential and may not be able to progress development programs as rapidly as otherwise possible. 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 through collaboration, license or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our products and product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our products and 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. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the U.S., 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 affect 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, in our licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the U.S. or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and product candidates and/or 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 may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs, including our GPCR program;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will be sufficient to protect our technology, provide us with a basis for commercially viable products or provide us with any competitive advantages;
-

- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws; or
- if issued, the patents under which we hold rights may not be valid or enforceable.

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

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisers 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 U.S. 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. We expect to incur substantial costs in connection with our lawsuit against Par. In addition, our lawsuit against such an entity could result in a finding that some or all of the claims of one or more of our relevant patents are invalid, unenforceable and/or not infringed, and could also result in a generic version of OMIDRIA being launched after the expiration of the mandatory three-year clinical data exclusivity for OMIDRIA. An adverse outcome in such legal action could have a material negative effect on our financial condition, results of operations and/or stock price.

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. It may not be feasible to detect and undertake patent enforcement action to stop infringing activity by a number of individual entities, each on a small scale, such as compounding pharmacies. Further, our industry has produced a large number of patents and it is not always clear which patents cover various types of products or methods of use. A third party may claim that we or our contract manufacturers are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in the alleged infringing activity, including making, using or selling our products and 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 contractors to stop the activities covered by the patents. In addition, if we or our contract manufacturers are found to have violated a third party's patent, we or our contract manufacturers could be ordered to pay damages to the other party. We have agreed to or may agree to indemnify our contract manufacturers against certain patent infringement claims and thus may be responsible for any of their costs associated with such claims and actions. If we were sued for patent infringement, we would need to demonstrate that our products and product candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we be unable to do this. Proving invalidity, in particular, is difficult since it requires clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Although we have conducted searches of third-party patents with respect to our programs, we have not obtained written freedom to operate opinions for our programs and may not have identified all relevant third-party patents. Consequently, we cannot be certain that third-party patents containing claims covering our products, product candidates, programs, technologies or methods do not exist, have not been filed, or could not be filed or issued.

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.

Our competitors may develop products that are less expensive, safer or more effective, or which may otherwise diminish or eliminate the commercial success of any products that we may commercialize.

We may not achieve commercial success if our competitors, many of whom have significantly more resources and experience than we, market products that are safer, more effective, less expensive or faster to reach the market than OMIDRIA or any future products that we may develop and commercialize. Our competitors also may market a product that proves to be unsafe or ineffective, which may affect the market for our competing product, or future

product, regardless of the safety or efficacy of our product. The failure of OMIDRIA or any other future product that we may market 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, our financial condition and our results of operations.

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

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance

policies other than on the life of Gregory A. Demopulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, without having a readily available and appropriate replacement could delay the execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

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

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

We may encounter difficulties managing our growth, which could delay our business plans or adversely affect our results of operations.

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 manage effectively 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. Additionally, our inability to manage growth effectively could cause our operating costs to grow even faster than we currently are anticipating.

Product liability claims may damage our reputation and, if insurance proves inadequate, these claims may harm our business.

We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product's safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with commercialization of our products and 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 or maintain such insurance on acceptable terms or that we will be able to secure and maintain increased coverage if the commercialization of OMIDRIA or our product candidates progresses, or that future claims against us will be covered by our product liability insurance. Further, our product liability 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.

Our preclinical programs may not produce product candidates that are suitable for clinical trials or that can be successfully commercialized or generate revenue through partnerships.

We must complete successfully preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before commencing clinical trials for any product candidate. Many pharmaceutical and biological products do not successfully complete preclinical testing and, even if preclinical testing is successfully completed, may fail in clinical trials. In addition, there can be no assurance that positive results from preclinical studies will be predictive of results obtained from subsequent preclinical studies or clinical trials. We also cannot be certain that any product candidates that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

We rely on third parties to conduct portions of our preclinical research and clinical trials. If these third parties do not perform as contractually required or otherwise expected, or if we fail to adequately supervise or monitor these parties, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We rely on third parties, such as CROs, medical and research institutions and clinical investigators, to conduct a portion of our preclinical research and assist us in conducting our clinical trials. Nonetheless, we are responsible for confirming that our preclinical research and clinical trials are conducted in accordance with applicable regulations, the relevant trial protocol and within the context of approvals by an Institutional Review Board or Ethics Committee, and we may not always be successful in ensuring such compliance. Our reliance on these third parties does not relieve us of responsibility for ensuring

compliance with FDA and other regulations and standards for conducting, monitoring, recording and reporting the results of preclinical research and clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical and clinical development processes may be extended, delayed, suspended or terminated, and we may not be able to commercialize or obtain regulatory approval for our product candidates.

We may need to maintain licenses for active ingredients from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates.

Should we decide to use active pharmaceutical ingredients in any of our product candidates that are proprietary to one or more third parties, such as our PDE7 program (OMS527) or our plasmin program (OMS616), we would need to maintain licenses to those active ingredients from those third parties. If we are unable to continue to access rights to these active ingredients prior to conducting 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 maintain continued 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.

The terms of our debt facility place restrictions on our operating and financial flexibility and, if we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

We have borrowed $50.0 million under the Oxford/EWB Loan Agreement. As collateral for this loan, we pledged substantially all of our assets other than intellectual property (with the exception of the proceeds derived from any intellectual property). The Oxford/EWB Loan Agreement restricts our ability to, among other things, incur indebtedness, grant liens, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, repurchase stock, license our intellectual property for a limited set of our programs without lender approval, pledge our intellectual property and engage in significant business transactions such as a change of control. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. The Oxford/EWB Loan Agreement also requires us to achieve certain minimum net revenue amounts from OMIDRIA through the end of 2018 and to maintain at least $10.0 million in cash and cash equivalents during the term of the Oxford/EWB Loan Agreement. The failure to satisfy these or other obligations under the Oxford/EWB Loan Agreement would allow the lenders to declare a default. If we default under the Oxford/EWB Loan Agreement, the lenders may have the right to accelerate all of our repayment obligations under the Oxford/EWB Loan Agreement and to take control of our pledged assets, which include our cash, cash equivalents and short-term investments. Further, if we are liquidated, the lenders' 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 Oxford/EWB Loan Agreement includes the occurrence of any material adverse effect upon our business operations, properties, assets, results of operations or financial condition, taken as a whole with respect to our viability, that would reasonably be expected to result in our inability to repay the loan. If either lender declares all obligations under the Oxford/EWB Loan Agreement immediately due and payable upon the occurrence of any event that the lender interprets as constituting an event of default as defined under the Oxford/EWB Loan Agreement, including but not limited to the lender concluding that a material adverse change has occurred as defined under the Oxford/EWB Loan Agreement, we will be required to repay the loan immediately or to attempt to reverse the declaration through negotiation or litigation. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline. If we raise any additional debt financing, the terms of such debt could further restrict our operating and financial flexibility.

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

Our research operations produce hazardous waste products, which include chemicals and radioactive and biological materials. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply with applicable legal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. We generally contract with third parties for the disposal of such substances and store our low-level radioactive waste at our facility 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.

Cyber-attacks or other failures in telecommunications or information technology systems could result in information theft, data corruption and significant disruption of our business operations.

We utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Risks Related to Our Common Stock

Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.

During the 12-month period ended December 31, 2015, our stock traded as high as $30.23 per share and as low as $10.48 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to numerous factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing shareholders would experience further dilution.

To the extent that we raise additional funds by issuing equity securities, including pursuant to our Sales Agreement with JonesTrading, our shareholders would experience dilution, which may be significant and could cause the market price of our common stock to decline significantly. In addition, as of March 10, 2016 approximately 10.1 million shares of common stock that are either subject to outstanding warrants or outstanding options may become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements. In addition, as of March 10, 2016 we also have approximately 2.2 million shares of common stock reserved for future issuance under our employee benefit plans that are not subject to outstanding options. If the holders of these outstanding warrants and/or options to purchase our common stock elect to exercise some or all of them, or if the shares subject to our employee benefit plans are issued and become eligible for sale in the public market, our shareholders would experience dilution and the market price of our common stock could decline.

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

Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of 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 10% 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 acquirers to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to

replace or remove our current management by making it difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We have never declared or paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

Our business requires significant funding. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Additionally, under the Oxford/EWB Loan Agreement, we have agreed not to pay any dividends. 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 the sole source of potential gain for shareholders in the foreseeable future, and an investment in our common stock for dividend income should not be relied upon.

ITEM 1B. UNRESOLVED STAFF COMMENTS
Not applicable.

ITEM 2. PROPERTIES
We lease approximately 83,000 square feet for our principal office and laboratory space in the building located at 201 Elliott Avenue West, Seattle, Washington, or The Omeros Building, which includes approximately 13,760 square feet of laboratory space that we are subleasing to a third party. The lease term for our space is through November 2027. We also have two options to extend the lease term, each by five years. The annual base rent due under the lease for our principal office and laboratory space is $4.1 million for 2016, $4.2 million for 2017 and $4.3 million for 2018 and will increase by approximately 2.3% each year thereafter. In addition, we are responsible for paying our proportionate share of the building's utilities, taxes, insurance and maintenance as well as a property management fee.
We have a right of first refusal for the premises that we do not currently lease as well as a right of first offer for specified premises in The Omeros Building. If at any time during the term of the lease our space requirements exceed the available space in The Omeros Building, the landlord will relocate us to a new building under a build-to-suit lease with no termination penalty payable under our existing lease, subject to the negotiation of a mutually acceptable build-to-suit lease. In addition, beginning with the sixth year of the lease term, if we request from the landlord additional space in The Omeros Building with a minimum square footage specified in the lease and the landlord is unable to provide such additional space to us, we may terminate the lease without payment of any termination fees other than the unamortized portion of a $3.0 million lease incentive paid to us by the landlord when we entered the lease. We have the right to terminate the lease beginning with year nine of the lease term, subject to the payment of a lease termination fee. If we terminate the lease during years nine or 10, the termination fee is equal to 30% of the unamortized tenant improvements and 100% of the unamortized lease incentive. If we terminate the lease any time after year 10 of the term, the termination fee is equal to 20% of the unamortized tenant improvements and 100% of the unamortized lease incentive. We believe that these facilities we lease currently are sufficient for our anticipated near-term needs.

ITEM 3. LEGAL PROCEEDINGS
In July 2015, we received a Notice Letter from Par that Par filed an ANDA containing a Paragraph IV Certification under the Hatch-Waxman Act and seeking approval from the FDA to market a generic version of OMIDRIA prior to the expiration of three Omeros patents, U.S. Patent Nos. 8,173,707, 8,586,633 and 9,066,856, which relate to OMIDRIA and that are listed in the FDA's Orange Book for OMIDRIA, or the Orange Book Patents. These patents were granted following review by the U.S. Patent and Trademark Office, or USPTO, are presumed to be valid under governing law, and can only be invalidated in federal court with clear and convincing evidence. Following receipt of the Paragraph IV Notice Letter we filed a patent infringement lawsuit against Par in the U.S. District Court for the District of New Jersey on September 2, 2015 and a patent infringement lawsuit against Par in the U.S. District Court for the District of Delaware on September 3, 2015. Based on our decision to pursue the action in federal court in Delaware, we voluntarily dismissed the complaint filed in the U.S. District Court for the District of New Jersey. The complaint that we filed in the U.S. District Court for the District of Delaware has been served on Par and Par has filed an answer asserting defenses and counterclaims for declaratory judgment of patent invalidity and non-infringement. The lawsuits were filed under the Hatch-Waxman Act alleging Par's infringement of the three Orange Book Patents. We intend to seek leave to amend the lawsuit to assert a fourth patent that issued after Par's Notice Letter, and which was granted by the USPTO after the USPTO considered all alleged prior art that was identified by Par in its Paragraph IV Notice Letter. We have reviewed the assertions in Par's Paragraph IV Notice Letter and believe they do not have merit, and intend to prosecute vigorously our patent infringement claims against Par. Under the Hatch-Waxman Act, we were permitted to file suit within 45 days from receipt of Par's Notice Letter and thereby trigger a 30-month stay of the FDA's final approval of Par's ANDA. Our lawsuit against Par triggered such stay, which is expected to remain in effect until late January 2018.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on The Nasdaq Global Market under the symbol "OMER."

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

Year Ended December 31, 2015	High	Low
4th Quarter	$16.52	$10.69
3rd Quarter	$30.23	$10.48
2nd Quarter	$26.64	$17.62
1st Quarter	$27.64	$18.51

Year Ended December 31, 2014	High	Low
4th Quarter	$25.10	$11.18
3rd Quarter	$18.80	$12.12
2nd Quarter	$18.01	$9.76
1st Quarter	$14.69	$10.11

Holders

As of February 29, 2016, there were approximately 143 holders of record of our common stock.

Dividends

We have never declared or paid any cash dividends on our capital stock, and under the Oxford/EWB Loan Agreement we have agreed not to pay any dividends. We expect to retain all available funds and future earnings to fund the development and growth of our business and we do not anticipate paying any cash dividends in the foreseeable future.

Stock Performance Graph

The following graph compares the cumulative total shareholder return for our common stock (OMER), the Nasdaq Biotechnology Index (NBI) and the Nasdaq U.S. Benchmark TR Index (NQUSBT) for the period beginning December 31, 2010 and ending December 31, 2015. This graph assumes that $100 was invested on December 31, 2010 in our common stock, the Nasdaq Biotechnology Index and the Nasdaq U.S. Benchmark TR Index. It also assumes that any dividends were reinvested. The data shown in the following graph are not necessarily indicative of future stock price performance.

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

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the accompanying notes included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results to be expected in any future period.

	Year Ended December 31,				
	2015	2014	2013	2012	2011
	(In thousands, except per share and share data)				
Consolidated Statements of Operations and Comprehensive Loss Data:					
Revenue					
Product Sales	$13,264	$—	$—	$—	$—
Grant revenue	245	539	1,600	6,022	4,524
Total revenue	13,509	539	1,600	6,022	4,524
Costs and expenses:					
Cost of product sales	1,041	—	—	—	—
Research and development	48,379	47,946	36,297	31,922	23,718
Selling, general and administrative	35,327	22,601	15,819	10,985	8,216
Total costs and expenses	84,747	70,547	52,116	42,907	31,934
Loss from operations	(71,238)	(70,008)	(50,516)	(36,885)	(27,410)
Litigation settlement	—	—	12,500	—	—
Interest expense	(3,573)	(3,470)	(2,366)	(1,729)	(1,884)
Loss on early extinguishment of debt	(1,315)	—	—	—	—
Other income (expense), net	1,030	(195)	586	170	748
Net Loss	$(75,096)	$(73,673)	$(39,796)	$(38,444)	$(28,546)
Basic and diluted net loss per share	$(2.00)	$(2.22)	$(1.39)	$(1.59)	$(1.29)
Denominator for basic and diluted net loss per share	37,560,257	33,234.294	28,560,360	24,155,690	22,212,351

	As of December 31,				
	2015	2014	2013	2012	2011
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$28,263	$6,886	$14,101	$22,350	$24,570
Working capital	20,893	(9,274)	2,944	16,341	6,963
Restricted cash and investments	10,679	679	679	679	193
Total assets	48,995	10,834	16,535	26,575	26,982
Notes payable, net of discount	49,842	32,453	20,498	20,103	19,446
Accumulated deficit	(403,142)	(328,046)	(254,373)	(214,577)	(176,133)
Total shareholders' deficit	(26,234)	(42,654)	(18,384)	(6,531)	(5,554)

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

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

Overview

We are a biopharmaceutical company committed to discovering, developing and commercializing both small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Our marketed drug product OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3% was broadly launched in the U.S. in April 2015 for use during cataract surgery or intraocular lens, or IOL, replacement. OMIDRIA is derived from our proprietary PharmacoSurgery® platform, which is designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures. Our proprietary PharmacoSurgery platform is based on low-dose combinations of U.S. Food and Drug Administration-approved, or FDA-approved, therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. In our pipeline we have clinical-stage development programs focused on: complement-related thrombotic microangiopathies; complement-mediated glomerulopathies; Huntington's disease and cognitive impairment; addictive and compulsive disorders; and problems associated with urologic surgical procedures. In addition, we have a diverse group of preclinical programs and two additional platforms: one capable of unlocking new G protein-coupled receptor, or GPCR, drug targets and the other used to generate antibodies. For OMIDRIA and each of our product candidates and our programs, other than OMS103, we have retained control of all commercial rights.

Financial Summary

We recognized net losses of $75.1 million, $73.7 million, and $39.8 million for the years ended December 31, 2015, 2014 and 2013, respectively. Historically, these losses have been principally from expenses incurred in connection with research and development activities and beginning in 2014, selling activities associated with planning for and launching OMIDRIA in the U.S. also contributed to our operating expenses. During the year ended December 31, 2015, U.S. OMIDRIA revenues of $13.3 million helped offset a portion of our 2015 operating expenses. We expect our net losses to continue until such time as we derive sufficient revenues from sales of OMIDRIA and/or other sources, such as licensing and other revenues from our product candidates, that are sufficient to cover our expenses. As of December 31, 2015, our accumulated deficit was $403.1 million and total shareholders' deficit was $26.2 million. We also had $28.3 million in cash and cash equivalents and short-term investments at December 31, 2015.

Results of Operations

Revenue

Our revenue consists of U.S. product sales of OMIDRIA and revenue recognized in connection with third-party grant funding.

	Years Ended December 31,		
	2015	2014	2013
	(In thousands)		
Product sales, net	$13,264	$—	$—
Grant revenue:			
Small Business Innovative Research Grants (SBIR)	245	539	630

Vulcan Inc.	—	—	970
Total revenue	$13,509	$539	$1,600

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The increase in revenues for the year ended December 31, 2015 compared to the same period in 2014 was due to the broad U.S. launch of OMIDRIA in April 2015. The decrease in revenue for the year ended December 31, 2014 to 2013 was primarily due to lower revenue recognized from our GPCR program funding agreements with Vulcan and LSDF that were fully recognized in 2013.

Product Sales, Net

We record OMIDRIA product sales net of estimated chargebacks, rebates, distribution fees and product returns. These deductions are generally referred to as gross-to-net deductions. A summary of our 2015 gross-to-net provision and payments are as follows:

	Chargebacks and Rebates	Distribution Fees and Product Return Allowances	Total
	(In thousands)		
Balance as of December 31, 2014	$—	$—	$—
Provision related to current period sales	320	555	875
Payments for current period sales	(140)	(278)	(418)
Balance as of December 31, 2015	$180	$277	$457

Chargebacks and Rebates. Immediately following the launch of OMIDRIA, we entered into a Pharmaceutical Pricing Agreement with the Secretary of the U.S. Department of Health and Human Services, which enables entities that qualify for government pricing under the Public Health Services Act, or PHSA, to receive discounts on their qualified purchases of OMIDRIA. We subsequently entered into a Federal Supply Schedule, or FSS, agreement under which certain U.S. government purchasers receive a discount on eligible purchases of OMIDRIA. In October 2015, we entered into an agreement with an authorized 340B prime vendor entitling its customers to purchase OMIDRIA at a greater discount (i.e., sub-340B/sub-wholesale acquisition cost, or WAC), than those offered under our PHSA Pharmaceutical Pricing Agreement. We identify the entities that purchase OMIDRIA that are eligible for PHSA, FSS or 340B prime-vendor pricing and, utilizing our historical chargeback information and projected payer mix, we record a provision for estimated chargebacks for these entities at the time of sale. After our wholesalers have made a sale at an eligible purchaser under one of these agreements, they forward to us a chargeback for the difference between WAC and the applicable discounted price and we issue the wholesaler a credit memo against its outstanding receivable to us. We have also entered into a Medicaid Drug Rebate Agreement with CMS, which provides a rebate to participating states based on covered purchases of OMIDRIA. We record estimated Medicaid rebates based on our payer mix and historical information for OMIDRIA at the time of sale and the accrual is offset when we make payments to the participating states.

In October 2015, we launched the OMIDRIAssure Reimbursement Services Program. This program expands patient access to OMIDRIA by providing reimbursement support services related to OMIDRIA, free product based on the financial need of government-insured or uninsured patients and financial assistance for patients whose commercial insurance is inadequate to cover fully the cost of OMIDRIA. We monitor claims submitted and claims actually paid and, utilizing this information, we project claims and estimate rebates for the program at the time of sale to the wholesaler. As payments are made, we reduce the previously recorded accrual.

We expect future chargeback and rebate deductions as a percentage of product sales to increase based on our prime vendor agreement, the launch of OMIDRIAssure and increased volume of purchases eligible for government-mandated discounts and rebates.

Distribution Fees and Product Return Allowances. We pay our wholesalers a distribution fee for services they perform for us based on the dollar value of their purchases of OMIDRIA. We record a provision for these charges at the time of sale to the wholesaler and, quarterly, we make payments to our wholesalers. We expect distribution fees to continue to fluctuate in correlation with product sales.

We allow for the return of product up to 12 months past its expiration date or for product that is damaged or not used by our customers. In estimating product returns, we take into consideration our single-tier distribution model, our

expectation that product is typically not accumulated by healthcare providers based on the frequency of their reorders, OMIDRIA expiration dating, quantities of inventory in the wholesale channel, our experience to date and historical industry return rates. We record a provision for returns upon sale of OMIDRIA to our wholesalers. When a return is received, we issue a credit memo to the wholesaler against its outstanding receivable to us.

Research and Development Expenses

Our research and development expenses can be divided into three categories: direct external expenses, which include clinical research and development and preclinical research and development activities; internal, overhead and other expenses; and stock-based compensation expense.

Direct external expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations, CROs, clinical trial sites, collaborators, licensors and consultants and lab supplies. Costs are reported in preclinical research and development until the program enters the clinic. Internal, overhead and other expenses consist of personnel costs, overhead costs such as rent, utilities and depreciation and other miscellaneous costs. We do not generally allocate our internal resources, employees and infrastructure to any individual research project because we deploy them across multiple clinical and preclinical projects that we are advancing in parallel.

The following table illustrates our expenses associated with these activities:

	Years Ended December 31,		
	2015	2014	2013
	(In thousands)		
Direct external expenses:			
Clinical research and development:			
OMS824	$1,508	$10,974	$7,265
OMS721	15,852	8,064	1,996
OMIDRIA (OMS302)	4,396	5,294	4,477
Other clinical programs	37	144	439
Total clinical research and development	21,793	24,476	14,177
Preclinical research and development	1,383	2,252	4,149
Total direct external expenses	23,176	26,728	18,326
Internal, overhead and other expenses	20,226	16,464	14,383
Stock-based compensation expense	4,977	4,754	3,588
Total research and development expenses	$48,379	$47,946	$36,297

The decrease in direct external clinical research and development expenses during the year ended December 31, 2015 compared to 2014 was due primarily to reduced costs for our OMS824 program in connection with its 2014 clinical suspension and lower OMIDRIA clinical trial costs after our U.S. approval in May 2014. This decrease was partially offset by increased clinical trial costs for our OMS721 program as we advanced our Phase 2 trials in TMAs, including aHUS, and increased cost of manufacturing OMS721 clinical trial material.

In addition, internal, overhead and other expenses increased during year ended December 31, 2015 compared to 2014 due primarily to increased headcount.

The increase in direct external clinical research and development expenses during the year ended December 31, 2014 compared to 2013 was due primarily to higher expenses related to our Phase 1 and Phase 2 clinical trials evaluating OMS824 and OMS721 and to expenses related to our Phase 3 clinical trials evaluating OMIDRIA.

In addition, internal, overhead and other expenses increased for the year ended December 31, 2014 compared to the same period in 2013 due to increased headcount. The increase in stock-based compensation related to stock option grants resulted from annual employee performance reviews in 2014 and new hire grants.

At this time, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates due to the inherently unpredictable nature of our preclinical and clinical development activities and to the early stage of many of our preclinical development programs. Clinical development timelines, the probability of success and development costs can differ materially as new data becomes available and as expectations change. While we are currently focused on advancing our product development programs, our future research and development expenses will depend on the preclinical or clinical success of each product candidate, the outcome of our ongoing assessments of each program’s commercial potential, the commercial success of OMIDRIA, the results of future collaborations, if any, and our overall capital resources. We also cannot forecast with any degree of certainty which product candidates, if any, 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 are required to expend substantial resources in the development of our product candidates due to the lengthy process of completing clinical trials and seeking regulatory approval. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in our generation of further product revenue, could increase our research and development expenses and, in turn, could have a material adverse effect on our operations, financial condition and liquidity. Because of the factors above, we are not able to estimate with any certainty when or if we would recognize any net cash inflows from our research and development projects.

Selling, General and Administrative Expenses

Our selling, general and administrative (SG&A) expenses are comprised primarily of salaries, benefits, stock-compensation costs for sales, marketing, and other personnel not directly engaged in research and development, service fees incurred for our dedicated contracted sales force, marketing and selling expenses, professional and legal services, general corporate costs and an allocation of our occupancy costs.

	Years Ended December 31,		
	2015	2014	2013
	(In thousands)		
Selling, general and administrative expenses, excluding stock-based compensation expense	$30,723	$18,437	$13,155
Stock-based compensation expense	4,604	4,164	2,664
Total selling, general and administrative expenses	$35,327	$22,601	$15,819

The increase in selling, general and administrative expenses during the year ended December 31, 2015 compared 2014 was primarily due to increased sales and marketing costs incurred in connection with our third-party contracted OMIDRIA sales force maintained by inVentiv; marketing materials, events and conferences; and administrative and legal costs to support the broad U.S. market launch of OMIDRIA in April 2015.

The increase in selling, general and administrative expenses during the year ended December 31, 2014 compared to the same period of 2013 was primarily due to incremental expenses related to the preparation for the U.S. commercial launch of OMIDRIA, which includes the costs for obtaining and training our third-party contracted sales force, the design and creation of marketing materials and the costs related to attending trade shows and conferences; and increased costs related to additional employees and non-cash stock-based compensation. These increases were partially offset by reduced legal fees associated with the expenses incurred in 2013 in connection with the matter against our former insurer and the $1.1 million we paid in 2013 to the National Institute of Health, or NIH, in connection with its administrative review (see Note 9 to our Consolidated Financial Statements in this Annual Report on Form 10-K).

In December 2015, we amended our agreement with inVentiv and, effective January 1, 2016, hired as in-house employees the majority of our previously contracted field sales representatives. Under the amended agreement, inVentiv will continue to provide back-office sales management and systems support to us on a month-to-month basis. We anticipate that the costs resulting from the conversion will not be materially different than the overall costs incurred for the contracted field sales representatives and related systems support.

We expect our selling, general and administrative expenses for 2016 to increase slightly from 2015 in connection with commissions on OMIDRIA sales and legal costs in connection with defending our patents and pursuing our patent infringement claims related to Par’s efforts to obtain FDA approval for a generic version of OMIDRIA.

Litigation Settlement

In the year ended December 31, 2013, we received a $12.5 million litigation settlement payment from our former insurer related to their defense of, and coverage obligations related to, the Klein lawsuit. (See Note 9 to our Consolidated Financial Statements in this Annual Report on Form 10-K).

Interest Expense

	Years Ended December 31,		
	2015	2014	2013
	(In thousands)		
Interest Expense	$3,573	$3,470	$2,366

Interest expense was $3.6 million and $3.5 million for the years ended December 31, 2015 and 2014, respectively. Interest expense remained steady in 2015 compared to 2014 due to similar average balances outstanding and the same effective interest rate on our notes payable during 2015 and 2014.

Interest expense was $3.5 million and $2.4 million for the years ended December 31, 2014 and 2013, respectively. The increase in 2014 compared to 2013 was the result of a higher average outstanding balance on our notes payable during 2014 than 2013 due to additional borrowings of $12.7 million in March 2014.

Loss on Early Extinguishment of Debt

In December 2015, we entered into a new Loan and Security Agreement with Oxford and East West Bank, or the Oxford/EWB Loan Agreement. We accounted for the termination of the then existing notes payable as a debt extinguishment (see Note 7 to our Consolidated Financial Statements in this Annual Report on Form 10-K). Accordingly, we incurred a loss of $1.3 million associated with the unamortized loan maturity fee and the prepayment fee.

Other Income (Expense), Net

	Years Ended December 31,		
	2015	2014	2013
	(In thousands)		
Other Income (Expense), Net	$1,030	$(195)	$586

Other income (expense) principally includes sublease rental income and non-cash charges associated with modifications to common stock warrants that we had outstanding. The increase in other income during the year ended December 31, 2015 compared to 2014 is due to incremental sublease income earned in 2015 and an $863,000 warrant modification expense incurred in 2014 (see Note 10 to our Consolidated Financial Statements in this Annual Report on Form 10-K). The decrease in other income (expense) during the year ended December 31, 2014 compared to 2013 is due to the $863,000 of warrant modification expense being recognized in 2014, which is partially offset by incremental sublease rental income.

Financial Condition - Liquidity and Capital Resources

We generated net losses of $75.1 million, $73.7 million and $39.8 million in 2015, 2014 and 2013, respectively, and as of December 31, 2015, we had $28.3 million in cash, cash equivalents and short-term investments available for general corporate use. In addition, in restricted cash and investments we have $10.0 million that must be maintained in depository and investment accounts pursuant to the Oxford/EWB loan agreement and $679,000 used to secure a letter of credit for The Omeros Building Lease.

Future Funding Requirements

We expect to continue to incur losses until such time as OMIDRIA product sales, corporate partnerships and/or licensing revenues from products or programs are adequate to support our ongoing operating expenses and debt service. Until we are cash-flow positive, if at all, we will need to continue to raise additional funds through public or private equity securities sales including our ATM with JonesTrading (see “At Market Issuance Sale Agreement” below), through the issuance of additional debt, through corporate partnerships, through asset sales or through the pursuit of collaborations and licensing arrangements related to certain of our products or programs. These conditions raise a substantial doubt about our ability to continue as a going concern. If we are unable to raise additional capital when needed through one or more of the avenues previously listed, or upon acceptable terms, such failure would have a significant negative impact on our financial condition. Should it be necessary to manage our operating expenses, we would reduce our projected cash requirements through reduction of our expenses by delaying clinical trials, reducing

selected research and development efforts, or implementing other restructuring activities.

Our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern in their report on our consolidated financial statements for the year ended December 31, 2015. A “going concern” opinion means, in general, that our independent registered public accounting firm has substantial doubt about our ability to continue our operations without additional infusions of capital from external sources. Our ability to continue as a going concern depends, in large part, on our ability to generate positive cash flow from operations and obtain additional financing, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

Cash Flow Data

	Years ended December 31,		
	2015	2014	2013
	(In thousands)		
Cash provided by (used in):			
Operating activities	$(65,209)	$(58,044)	$(29,695)
Investing activities	(20,606)	6,157	7,909
Financing activities	86,826	50,857	21,650

Operating Activities. Net cash used in operating activities increased for the year ended December 31, 2015 by $7.2 million as compared to the same period in 2014. Our 2015 net loss increased by $1.4 million from 2014 due primarily to the OMIDRIA gross margin of $12.2 million being offset by a $12.7 million increase in selling, general and administrative expenses associated with the U.S. launch of OMIDRIA. The other primary activity impacting the increase in net cash used in operating activities between the comparative periods is a $6.1 million increase in receivables related to OMIDRIA sales, which generally have up to 30-90 day terms.

Net cash used in operating activities increased for the year ended December 31, 2014 by $28.3 million as compared to the same period in 2013. This increase was primarily related to the increase in our net loss by $33.9 million from 2013 in large part due to an $18.4 million increase in operating expenses and the $12.5 million we received in 2013 in the litigation settlement with our former insurer. Other activities impacting the increase in net cash used in operating activities between the comparative periods was an increase of $6.6 million in accounts payable and accrued expenses in 2014 compared to 2013 and a $2.6 million decrease in the growth of deferred rent between 2014 and 2013.

Investing Activities. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and proceeds from the sale of short-term investments, thus causing a shift between our cash and cash equivalents and short-term investment balances. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider the fluctuations between cash, cash equivalents and our short-term investment balances to be important to the understanding of our liquidity and capital resources. The remaining component of cash flows from investing activities is the purchase of property and equipment.

Net cash used in investing activities in the year ended December 31, 2015 was $20.6 million, an increase of $26.8 million from 2014, primarily due to the purchase of short-term investments with the $79.1 million of net proceeds received from the sale of common stock and pre-funded warrants in our public offering in February 2015 and $22.3 million in net proceeds from the Oxford/EWB loan. These purchases were partially offset by the sale of $71.4 million of short-term investments to provide cash for operating activities.

Net cash provided from investing activities for the year ended December 31, 2014 was $6.2 million, a decrease of $1.8 million from 2013. Of the decrease in cash provided by investing activities between the comparative periods, $1.9 million was from the purchase of short-term investments year-over-year exceeding our sale of short-term investments.

Financing Activities. Net cash provided by financing activities in the year ended December 31, 2015 was $86.8 million, an increase of $36.0 million over the same period in 2014 primarily due to the $79.1 million of net proceeds received from the sale of 3.4 million shares of common stock and pre-funded warrants to purchase 749,250 shares of common stock in our public offering in February 2015 and the net additional borrowings of $22.3 million under the Oxford/EWB Loan Agreement. During the 2015 period, we also received $2.9 million upon the exercise of employee stock options and warrants. These additions were offset by the purchase of $10.0 million of restricted investments pursuant to the Oxford/EWB loan agreement and $7.4 million in principal payments under the Loan and Security

Agreement (the Oxford/MidCap Loan Agreement) with Oxford and MidCap Financial SBIC, LP (MidCap) prior to entering into the Oxford/EWB Loan Agreement.

Net cash provided from financing activities in the year ended December 31, 2014 was $50.9 million, a $29.2 million increase from 2013. In March 2014, we received $37.8 million of net proceeds from the sale of 3.5 million shares of common stock in a public offering and $12.7 million from net additional borrowings under the Oxford/MidCap Loan Agreement. During the 2014 period, we also received $1.9 million upon the exercise of employee stock options and paid $1.5 million of principal on notes payable prior to entering into the Oxford/MidCap Loan Agreement.

Loan and Security Agreement

In December 2015, we entered into the Oxford/East West Loan Agreement pursuant to which we borrowed $50.0 million. We can borrow an additional $20.0 million in two tranches of $10.0 million each through June 30, 2017, contingent upon the satisfaction of certain conditions including minimum net revenue from OMIDRIA. We used $27.3 million of the loan proceeds to repay all of the amounts owed by us under our then-outstanding loan from Oxford/Midcap and, after deducting all loan initiation and outstanding interest on the Oxford/MidCap Loan Agreement, we received $22.3 million in net proceeds.

The Oxford/EWB Loan Agreement requires monthly interest-only payments at an annual rate of 9.25% through July 1, 2017. Beginning August 1, 2017, monthly principal and interest payments of approximately $1.9 million are due on the original $50.0 million we borrowed through the maturity date of January 1, 2020. In addition, the Oxford/EWB Loan Agreement requires a $3.8 million loan maturity fee upon full repayment of the initial $50.0 million borrowed and $525,000 for each additional $10.0 million borrowed. We may prepay the outstanding principal balance in its entirety at any time if we pay an additional fee equal to 1.0% of the then-outstanding principal balance. As security under the Oxford/EWB Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property (other than the proceeds derived from any intellectual property).

The Oxford/EWB Loan Agreement contains covenants that require us to maintain $10.0 million in restricted cash and certain eligible term investments, to meet an annual OMIDRIA revenue minimum for 2016 and quarterly OMIDRIA revenue minimums in 2017 and 2018, and to establish an at-the-market, or ATM, equity facility that we established on January 6, 2016 (see Note 10). The Oxford/EWB Loan Agreement also contains covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, repurchase stock, license our intellectual property for a limited set of our programs without lender approval or pledge our intellectual property. Additionally, the Oxford/EWB Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breaches, occurrence of a material adverse effect (MAE, as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgments, and a change of control. The occurrence of an event of default could result in the acceleration of the Oxford/EWB Loan Agreement and, under certain circumstances, could increase our interest rate by 5.0% per annum during the period of default. MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our inability to repay any portion of the loans in accordance with the terms of the Oxford/EWB Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the enforceability of any material provision of the Oxford/EWB Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce their rights and remedies under the Oxford/EWB Loan Agreement or related agreements. As of December 31, 2015, we were not in default under the Oxford/EWB Loan Agreement described above.

At Market Issuance Sales Agreement

In January 2016, as required by the Oxford/EWB Loan Agreement, we entered into an At Market Issuance Sales Agreement, or the ATM Agreement, with JonesTrading Institutional Services LLC, or JonesTrading, pursuant to which we may direct JonesTrading to sell shares of our common stock with an aggregate offering price of up to $100.0 million directly on The Nasdaq Global Market, through or to a market maker other than on an exchange or in negotiated transactions. Any sales made under the ATM Agreement are based solely on our instructions and JonesTrading will receive a 1.7% commission from the gross proceeds. The ATM Agreement may be terminated by either party at any time upon 10 days' notice to the other party, or by JonesTrading at any time in certain circumstances including the occurrence of a material adverse effect to Omeros.

Contractual Obligations and Commitments

The following table presents a summary of our contractual obligations and commitments as of December 31, 2015.

	Payments Due Within				
	1 Year	2-3 Years	4-5 Years	More than 5 Years	Total
	(In thousands)				
Operating leases	$4,106	$8,447	$8,800	$33,263	$54,616
Capital leases (principal and interest)	86	165	62	—	313
Notes payable (principal and interest)	4,625	36,030	22,478	—	63,133
Goods & Services	$1,396	$—	$—	$—	1,396
Total	$10,213	$44,642	$31,340	$33,263	$119,458

Operating Leases

We lease our office and laboratory space in The Omeros Building under a lease agreement with BMR - 201 Elliott Avenue LLC. The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of December 31, 2015, the remaining aggregate non-cancelable rent payable under the initial term of the lease, excluding common area maintenance and related operating expenses, is $54.5 million.

We also rent equipment under various operating lease agreements. As of December 31, 2015, the remaining aggregate non-cancellable rent payable under these equipment leases is $76,000.

Notes Payable

Refer to “Liquidity-Loan and Security Agreement” above.

Goods & Services

As of December 31, 2015, Patheon was completing the analytical testing required to transfer OMIDRIA commercial product costing $1.3 million to us. We anticipate receiving the product during the first quarter of 2016 and the product dating will allow the product to be sold through at least the third quarter of 2018. This is the final commercial supply of OMIDRIA that Patheon will be available to produce in its facility currently approved for the manufacture of OMIDRIA.

We have entered into a non-exclusive agreement with Hospira Worldwide, Inc., or Hospira, for the ongoing commercial supply of OMIDRIA and we are currently completing the manufacturing process transfer, process validation and approval of Hospira as a manufacturing site for OMIDRIA. We anticipate Hospira will be able to provide OMIDRIA commercial product to us beginning in the first part of 2017. We have no firm purchase commitments outstanding under this agreement as of December 31, 2015.

We may also be required, in connection with in-licensing or asset acquisition agreements, to make certain royalty and milestone payments and we cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. Therefore, such payments are not included in the table above. See Note 9 to our Consolidated Financial Statements in this Annual Report on Form 10-K for a description of the agreements that include these royalty and milestone payment obligations.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our consolidated financial statements, in conformity with generally accepted accounting principles, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from those estimates. An accounting policy is considered critical if it is important to a company’s financial condition and results of operations and if it requires the exercise of significant judgment and the use of estimates on the part of management in its application. Although we believe that our judgments and estimates are appropriate, actual results may differ materially from our estimates.

We believe the following to be our critical accounting policies because they are both important to the portrayal of our financial condition and results of operations and they require critical judgment by management and estimates about matters that are uncertain:

- revenue recognition;

- research and development expenses, primarily clinical trial expenses; and
- stock-based compensation.

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

Revenue Recognition

Our revenues are comprised of product sales of OMIDRIA and amounts earned for services under grants from third parties. Revenue is recognized when there is persuasive evidence that an arrangement exists, product title and risk of loss is passed or the service has been provided, the price is fixed or determinable and collection is reasonably assured. We record OMIDRIA product revenue upon delivery to our wholesalers. Product sales to a wholesaler are not recorded if we determine that the wholesaler's on-hand OMIDRIA inventory, based on inventory information we regularly receive from our wholesalers, exceeds approximately eight weeks of projected demand.

Product sales are recorded net of estimated chargebacks and rebates, wholesaler fees for distribution services and estimated product returns. Accruals, which require a substantial degree of judgment, are established for these deductions when revenue is recognized and actual amounts incurred are offset against the applicable accruals. If actual results vary from our estimates, we may need to adjust our accruals which could have an effect on our results of operations in the period of the adjustment. We reflect each of these accruals as either a reduction in the related account receivable or as an accrued liability, depending on how the accrual is settled.

Chargebacks and Rebates: Provisions for chargebacks are determined utilizing historical and projected payer mix and sale-through and inventory on-hand information received directly from wholesalers. Chargebacks are generally settled within four weeks of recording product sales revenue.

We provide reimbursement support services and financial assistance in the form of a rebate on behalf of patients whose commercial insurance is inadequate to cover the full cost of OMIDRIA. We apply an experience ratio to product sales to determine the rebate accrual. This experience ratio is reviewed and updated periodically to reflect actual results.

Distribution Fees and Product Return Allowances. We pay our wholesalers a distribution fee for services that they perform for us based on the WAC value of their purchases of OMIDRIA. We record a provision against product sales for these charges at the time of sale to the wholesaler.

For all wholesalers and health care providers, we allow for the return of product up to 12 months past its expiration date if the product is damaged or if the product is unused by the ASC or hospital. In estimating product returns allowances, we take into consideration our single-tier distribution model and our belief that product is typically not held by the healthcare providers based on the frequency of their reorders. We also consider inventory in the wholesale channel, our return experience to date, the remaining shelf life of product we have previously sold and historical industry return rates.

Research and Development Expenses

Research and development costs are comprised primarily of costs for personnel, including salaries, benefits and stock compensation; an allocation of our occupancy costs; clinical study costs; contracted research; manufacturing; consulting arrangements; depreciation; materials and supplies; milestones; and other expenses incurred to sustain our overall research and development programs. Clinical trial expenses for investigational sites require certain estimates. We estimate these costs based on a cost per patient that varies depending on the clinical trial site. As actual costs become known to us, we adjust our estimates; these changes in estimates may result in understated or overstated expenses at a given point in time. Research and development costs are expensed as incurred.

Advanced payments for goods or services that will be used or rendered for future research and development activities are deferred and then recognized as an expense as the related goods are delivered or as the services are performed, or when the goods or services are no longer expected to be provided.

Stock-Based Compensation

Stock-based compensation expense is recognized for all share-based payments made to employees, directors and non-employees based on estimated fair values. The fair value of our stock options is calculated using the Black-Scholes option valuation model, which requires assumptions, including volatility, forfeiture rates and expected

option life. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense for new awards may differ materially from that recorded for existing awards and stock-based compensation for non-employees will vary as the awards are re-measured over the vesting term.

As stock-based compensation expense is based on options ultimately expected to vest, the expense has been reduced for estimated forfeitures. We estimate forfeitures for expense recognition based on our historical experience. Groups of employees that have similar historical forfeiture behavior are considered separately. We use the straight-line method to allocate compensation cost to reporting periods over each optionee's respective requisite service period for employees and directors, which is generally the vesting period.

Stock options granted to non-employees are accounted for using the fair-value approach using the Black-Scholes option-pricing model and are re-measured over the vesting term as earned. The estimated fair value is charged to expense over the applicable service period.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU 2016-02 related to lease accounting. This standard requires lessees to recognize a right-of-use asset and a lease liability for most leases. This standard must be applied using a modified retrospective transition and is effective for all annual and interim periods beginning after December 15, 2018. Earlier adoption is permitted. We are evaluating how this new standard will impact the presentation of our financial statements and related disclosures.

In July 2015, FASB issued ASU 2015-11 related to simplifying the measurement of inventory. This standard requires inventory to be measured at the lower of cost or net realizable value. This standard must be applied prospectively and is effective for all annual and interim periods beginning after December 15, 2016. Earlier application is permitted as of the beginning of an interim or annual reporting period. This standard is not expected to have a material impact on the presentation of the Company's financial position.

In August 2014, FASB issued ASU No. 2014-15 related to disclosure of an entity's ability to continue as a going concern. This standard requires management to evaluate whether substantial doubt exists regarding the entity's ability to continue as a going concern at each reporting period for a duration of one year after the date the financial statements are issued or available to be issued. The standard establishes certain required disclosures if substantial doubt exists. This standard must be applied prospectively and is effective for interim and annual periods beginning after December 15, 2016. We will review the impact of the standard upon our disclosures, if applicable, beginning in 2017.

In May 2014, FASB issued ASU No. 2014-09 related to the recognition of revenue that supersedes existing guidance. This standard clarifies the principles for recognizing revenue utilizing a five-step process. This standard must be applied retroactively to each prior reporting period presented, or retrospectively with the cumulative effect of applying the standard recognized in the period adopted. As amended, the standard is effective for interim and annual periods beginning after December 15, 2017 and cannot be adopted before that effective date. We are currently evaluating the impact that this standard may have on our financial statements once it is adopted.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is primarily confined to our investment securities and notes payable. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities. As of December 31, 2015, we had cash, cash equivalents and short-term investments of $28.3 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. 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 and, with our current portfolio of short term investments, we are not exposed to potential loss due to changes in interest rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2015. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2015, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

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

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

Our management, with the participation of our principal executive and principal financial officers, conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 framework). Based on the results of this assessment and on those criteria, our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Ernst & Young LLP has independently assessed the effectiveness of our internal control over financial reporting as of December 31, 2015 and its report is included below.

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during our fourth fiscal quarter of 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders of Omeros Corporation

We have audited Omeros Corporation's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Omeros Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Omeros Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Omeros Corporation as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, shareholders' deficit, and cash flows for each of the three years in the period ended December 31, 2015 of Omeros Corporation and our report dated March 15, 2016 expressed an unqualified opinion thereon that included an explanatory paragraph regarding Omeros Corporation's ability to continue as a going concern.

/s/ Ernst & Young LLP

Seattle, Washington

March 15, 2016

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ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2016 Annual Meeting of Shareholders and is incorporated herein by reference. Certain information required by this item concerning executive officers is set forth in Part I of this Annual Report on Form 10-K in "Business-Executive Officers and Key Employees."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2016 Annual Meeting of Shareholders and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

Except for the information set forth below, the information required by this item will be contained in our definitive proxy statement issued in connection with the 2016 Annual Meeting of Shareholders and is incorporated herein by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain information regarding our equity compensation plans in effect as of December 31, 2015:

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by security holders:			
2008 Equity Incentive Plan (1)	6,875,754	$ 9.38	1,724,987
Amended and Restated 1998 Stock Option Plan	1,434,412	1.17	—
nura inc.	69	10.63	—
Total	8,310,235	$ 7.97	1,724,987

(1) Our 2008 Equity Incentive Plan (the 2008 Plan) provides for the grant of incentive and nonstatutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, directors and consultants and subsidiary corporations' employees and consultants. The 2008 Plan also allows any shares returned under our Amended and Restated 1998 Stock Option Plan (the 1998 Plan), as a result of cancellation of options or repurchase of shares issued pursuant to the 1998 Plan, to be issued under the 2008 Plan. In addition, our 2008 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each year equal to the lower of: (i) five percent of the outstanding shares of our common stock on the last day of the preceding year; (ii) 1,785,714 shares; and (iii) such other amount as our board of directors may determine. On January 1, 2016, an additional 1,785,714 shares became available for future issuance under our 2008 Plan in accordance with the annual increase. These additional shares from the annual increase are not included in the table above.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2016 Annual Meeting of Shareholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2016 Annual Meeting of Shareholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

1. Financial Statements

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

2. Financial Statement Schedules

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

3. Exhibits

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OMEROS CORPORATION
/s/ GREGORY A. DEMOPULOS, M.D.
Gregory A. Demopulos, M.D.
President, Chief Executive Officer
and Chairman of the Board of Directors

Dated: March 15, 2016

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

Signature	Title	Date
/s/ GREGORY A. DEMOPULOS, M.D. Gregory A. Demopulos, M.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 15, 2016
/s/ MICHAEL A. JACOBSEN Michael A. Jacobsen	Vice President, Finance, Chief Accounting Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 15, 2016
/s/ RAY ASPIRI Ray Aspiri	Director	March 15, 2016
/s/ THOMAS J. CABLE Thomas J. Cable	Director	March 15, 2016
/s/ PETER A. DEMOPULOS, M.D. Peter A. Demopulos, M.D.	Director	March 15, 2016
/s/ ARNOLD C. HANISH Arnold C. Hanish	Director	March 15, 2016
/s/ LEROY E. HOOD, M.D., PH.D. Leroy E. Hood, M.D., Ph.D.	Director	March 15, 2016
/s/ RAJIV SHAH, M.D. Rajiv Shah, M.D.	Director	March 15, 2016

OMEROS CORPORATION
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
Omeros Corporation

We have audited the accompanying consolidated balance sheets of Omeros Corporation as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, shareholders' deficit and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Omeros Corporation at December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Omeros Corporation's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 15, 2016 expressed an unqualified opinion thereon.
/s/ Ernst & Young LLP

Seattle, Washington
March 15, 2016

OMEROS CORPORATION
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$1,365	$354
Short-term investments	26,898	6,532
Receivables	6,517	392
Inventory	472	568
Prepaid expense	1,894	1,195
Total current assets	37,146	9,041
Property and equipment, net	951	782
Restricted cash and investments	10,679	679
Other assets	219	332
Total assets	$48,995	$10,834
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$6,428	$4,915
Accrued expenses	9,752	7,070
Current portion of notes payable	73	6,330
Total current liabilities	16,253	18,315
Notes payable, net	49,769	26,123
Deferred rent	9,207	9,050
Commitments and contingencies (Note 9)		
Shareholders' deficit:		
Preferred stock, par value $0.01 per share, 20,000,000 authorized and none issued at December 31, 2015 and 2014.	—	—
Common Stock, par value $0.01 per share, 150,000,000 shares authorized at December 31, 2015 and 2014; 38,040,891 and 34,185,464 issued and outstanding at December 31, 2015 and December 31, 2014, respectively.	380	342
Additional paid-in capital	376,528	285,050
Accumulated deficit	(403,142)	(328,046)
Total shareholders' deficit	(26,234)	(42,654)
Total liabilities and shareholders' deficit	$48,995	$10,834

See notes to consolidated financial statements

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

	Year Ended December 31,		
	2015	2014	2013
Revenues:			
Product sales, net	$13,264	$—	$—
Grant revenue	245	539	1,600
Total revenue	13,509	539	1,600
Costs and expenses:			
Cost of product sales	1,041	—	—
Research and development	48,379	47,946	36,297
Selling, general and administrative	35,327	22,601	15,819
Total costs and expenses	84,747	70,547	52,116
Loss from operations	(71,238)	(70,008)	(50,516)
Litigation settlement	—	—	12,500
Interest expense	(3,573)	(3,470)	(2,366)
Loss on early extinguishment of debt	(1,315)	—	—
Other income (expense), net	1,030	(195)	586
Net loss	$(75,096)	$(73,673)	$(39,796)
Comprehensive loss	$(75,096)	$(73,673)	$(39,796)
Basic and diluted net loss per share	$(2.00)	$(2.22)	$(1.39)
Weighted-average shares used to compute basic and diluted net loss per share	37,560,257	33,234,294	28,560,360

See notes to consolidated financial statements

OMEROS CORPORATION
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT
(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount			
Balance at December 31, 2012	25,897,483	$259	$207,787	$(214,577)	$(6,531)
Issuance of common stock, net of offering costs	3,903,004	39	16,081	—	16,120
Issuance of common stock utilizing At-The-Market Agreement, net of commissions	373,700	4	4,864	—	4,868
Issuance of common stock upon exercise of stock options	185,321	2	660	—	662
Stock-based compensation	—	—	6,252	—	6,252
Warrant modification	—	—	41	—	41
Net loss	—	—	—	(39,796)	(39,796)
Balance at December 31, 2013	30,359,508	304	235,685	(254,373)	(18,384)
Issuance of common stock, net of offering costs	3,500,000	35	37,719	—	37,754
Issuance of common stock upon exercise of warrants	28,653	—	68	—	68
Issuance of common stock upon exercise of stock options	297,303	3	1,797	—	1,800
Stock-based compensation	—	—	8,918	—	8,918
Warrant modification	—	—	863	—	863
Net loss	—	—	—	(73,673)	(73,673)
Balance at December 31, 2014	34,185,464	$342	$285,050	$(328,046)	$(42,654)
Issuance of common stock and pre-funded warrants, net of offering costs	3,444,831	34	79,042	—	79,076
Issuance of common stock upon exercise of warrants	133,240	1	1,435	—	1,436
Issuance of common stock upon exercise of stock options	277,356	3	1,420	—	1,423
Stock-based compensation	—	—	9,581	—	9,581
Net loss	—	—	—	(75,096)	(75,096)
Balance at December 31, 2015	38,040,891	$380	$376,528	$(403,142)	$(26,234)

See notes to consolidated financial statements

OMEROS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2015	2014	2013
Operating activities:			
Net loss	$(75,096)	$(73,673)	$(39,796)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss on early extinguishment of debt	1,315	—	—
Depreciation and amortization	209	317	302
Stock-based compensation expense	9,581	8,918	6,252
Non-cash interest expense	1,045	738	502
Warrant modification expense	—	863	41
Changes in operating assets and liabilities:			
Receivables	(6,125)	(13)	1,555
Inventory	96	(568)	—
Prepaid expenses and noncurrent assets	(586)	(987)	84
Accounts payable and accrued expenses	4,195	5,459	(1,169)
Deferred revenue	—	—	(970)
Deferred rent	157	902	3,504
Net cash used in operating activities	(65,209)	(58,044)	(29,695)
Investing activities:			
Purchases and sales of property and equipment, net	(240)	(28)	(204)
Purchases of investments	(91,766)	(58,849)	(47,182)
Proceeds from the sale and maturities of investments	71,400	65,034	55,295
Net cash provided by (used in) investing activities	(20,606)	6,157	7,909
Financing activities:			
Proceeds from issuance of common stock and pre-funded warrants, net	79,076	37,754	20,988
Proceeds from borrowings under notes payable, net	22,329	12,699	—
Increase in restricted cash and investments	(10,000)	—	—
Repayments on notes payable	(7,438)	(1,464)	—
Proceeds upon exercise of stock options and warrants	2,859	1,868	662
Net cash provided by financing activities	86,826	50,857	21,650
Net increase (decrease) in cash and cash equivalents	1,011	(1,030)	(136)
Cash and cash equivalents at beginning of period	354	1,384	1,520
Cash and cash equivalents at end of period	$1,365	$354	$1,384
Supplemental cash flow information			
Cash paid for interest	$4,236	$2,674	$1,709
Reduction of equipment cost basis due to assets purchased with grant funding	$—	$80	$—
Property acquired under capital lease	$137	$200	$—

See notes to consolidated financial statements

OMEROS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1—Organization and Basis of Presentation

Organization

We are a biopharmaceutical company committed to discovering, developing and commercializing both small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Our first drug product OMIDRIA has been approved by the United States (U.S.) Food and Drug Administration (FDA) for use during cataract surgery or intraocular lens (IOL) replacement. We broadly launched OMIDRIA in the U.S. in April 2015.

Basis of Presentation

Our consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions have been eliminated. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP).

Segments

We operate in one segment. Management uses cash flow as the primary measure to manage our business and does not segment our business for internal reporting or decision-making.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant items subject to such estimates include revenue recognition, stock-based compensation expense and accruals for clinical trials and contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from these estimates.

Reclassifications

Certain reclassifications have been made to prior periods in the consolidated financial statements and the accompanying notes to conform with the current presentation, none of which impacted our net loss or working capital.

Liquidity and Capital Resources

We generated net losses of $75.1 million, $73.7 million and $39.8 million in 2015, 2014 and 2013, respectively, and as of December 31, 2015, we had $28.3 million in cash, cash equivalents and short-term investments available for general corporate use. In addition, in restricted cash and investments we have $10 million that must be maintained in depository and investment accounts pursuant to the new Loan and Security Agreement (the Oxford/EWB Loan Agreement) with Oxford and EastWest Bank (EWB) as well as $679,000 used to secure a letter of credit for the Omeros Building lease.

We expect to continue to incur losses until such time as OMIDRIA product sales, corporate partnerships and/or licensing revenues from products or programs are adequate to support our ongoing operating expenses and debt service. We are unable to predict if or when this may occur, and until it does occur, we will need to continue to raise additional funds through public or private equity securities sales including our ATM with JonesTrading (see Note 10 for further detail), through the issuance of additional debt, through corporate partnerships, through asset sales or through the pursuit of collaborations and licensing arrangements related to certain of our products or programs. These conditions raise a substantial doubt about our ability to continue as a going concern. If we are unable to become cash-flow positive or to raise additional capital as and when needed, or upon acceptable terms, such failure would have a significant negative impact on our financial condition.

The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Note 2—Significant Accounting Policies

Cash and Cash Equivalents, Short-Term Investments, and Restricted Cash and Investments

Cash and cash equivalents include highly liquid investments with a maturity of three months or less on the date of purchase. Short-term investment securities are classified as available-for-sale and are carried at fair value. Unrealized gains and losses, if any, are reported as a separate component of shareholders' deficit. Amortization, accretion, interest and dividends, realized gains and losses and declines in value judged to be other-than-temporary are included in other income (expense). The cost of securities sold is based on the specific-identification method. Investments in securities with maturities of less than one year, or those for which management intends to use the investments to fund current operations, are included in current assets. We evaluate whether an investment is other-than-temporarily impaired based on the specific facts and circumstances. Factors that are considered in determining whether an other-than-temporary decline in value has occurred include: the market value of the security in relation to its cost basis; the financial condition of the investee; and the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment. Restricted cash and investments are held in certificates of deposit and money-market funds.

Inventory

Inventory is stated at the lower of cost or market determined on a specific identification basis in a manner which approximates the first-in, first-out (FIFO) method. Costs include amounts related to third party manufacturing, transportation and internal labor and overhead. Capitalization of costs as inventory begins when the product candidate receives regulatory approval in the U.S. or the European Union (EU), which for OMIDRIA began upon U.S. regulatory approval in May 2014. We expense inventory costs related to product candidates as research and development expenses prior to receiving regulatory approval in the respective territory. Inventory is reduced to net realizable value for excess and obsolete inventories based on forecasted demand.

Receivables

Receivables relate primarily to sales of OMIDRIA to wholesalers and include reductions for estimated chargebacks, rebates, and product returns which are expected to be settled through reductions in receivables. Remaining receivables consist of amounts related to grants from the National Institutes of Health (NIH) and subleases for space in The Omeros Building. Considering the nature and historic collectability of our receivables, we concluded an allowance for doubtful accounts is not necessary as of December 31, 2015 and 2014.

Property and Equipment, net

Property and equipment are stated at cost and depreciation is calculated using the straight-line method over the estimated useful life of the assets, which is generally three to ten years. Equipment financed under capital leases is recorded as property and equipment and is amortized over the shorter of the useful lives of the related assets or the lease term. Expenditures for equipment purchased with grant funds are recorded as a reduction to the cost of the applicable equipment. Expenditures for repairs and maintenance are expensed as incurred.

Impairment of Long-Lived Assets

The carrying amount of long-lived assets is reviewed whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of these assets is measured by comparing the carrying value to future undiscounted cash flows the asset is expected to generate. If the asset is considered to be impaired, the amount of any impairment will be reflected in the results of operations in the period of impairment. We have not recognized any impairment losses for the years ending December 31, 2015, 2014 and 2013.

Deferred Rent

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

Revenue Recognition

Our revenues are comprised of product sales of OMIDRIA and amounts earned for services under grants from third parties. Revenue is recognized when there is persuasive evidence that an arrangement exists, product title and risk of

loss is passed to the customer or the service has been provided, the price is fixed or determinable and collection is reasonably assured.

Product Sales, Net

We record revenue from product sales when the product is delivered to our wholesalers. Product sales to a wholesaler are not recorded if we determine that the wholesaler's on-hand OMIDRIA inventory, based on inventory information we regularly receive from our wholesalers, exceeds approximately eight weeks of projected demand.

Product sales are recorded net of chargebacks and rebates, wholesaler distribution fees and estimated product returns. Accruals or allowances are established for these deductions when revenue is recognized, and actual amounts incurred are offset against the applicable accruals or allowances. We reflect each of these accruals or allowances as either a reduction in the related account receivable or as an accrued liability, depending on how the amount is settled.

Provisions for chargebacks are determined utilizing historical and projected payer mix and sale-through and inventory on-hand information received directly from wholesalers. Chargebacks are generally settled within four weeks of recording product sales revenue.

We provide reimbursement support services and financial assistance in the form of a rebate to patients whose commercial insurance is inadequate to cover the full cost of OMIDRIA. We apply an experience ratio to product sales to determine the rebate accrual. This experience ratio is reviewed and updated periodically to reflect actual results.

We allow for the return of product up to 12 months past its expiration date or for product that is damaged. In estimating product returns, we take into consideration our single-tier distribution model, our expectation that product is typically not held by the healthcare providers based on the frequency of their reorders, inventory in the wholesale channel, our return experience to date, the remaining shelf life of product we have previously sold and historical industry return rates.

We pay our wholesalers a distribution fee for services they perform on our behalf based on a contractual rate.

Research and Development

Research and development costs are comprised primarily of costs for personnel, including salaries, benefits and stock compensation; an allocation of our occupancy costs; clinical study costs; contracted research; manufacturing; consulting arrangements; depreciation; materials and supplies; milestones; and other expenses incurred to sustain our overall research and development programs. Research and development costs are expensed as incurred.

Advance payments for goods or services that will be used or rendered for future research and development activities are deferred and then recognized as an expense as the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided.

Patents

We generally apply for patent protection on processes and product candidates we or our licensors conceive or develop. Patent costs are comprised primarily of external legal fees, filing fees incurred to file patent applications, and periodic renewal fees to keep the patent in force and are expensed as incurred as a component of general and administrative expense.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses are comprised primarily of salaries, service fees incurred for our dedicated contracted sales force, benefits, and stock-compensation costs for sales, marketing, and other personnel not directly engaged in research and development. Additionally, SG&A includes marketing and selling expenses, professional and legal services; patent costs; depreciation, an allocation of our occupancy costs; and other general corporate expenses. Effective January 1, 2016, we converted our dedicated contracted sales force provided by a third party to Omeros employees.

Advertising

Advertising costs, which we consider to be media and marketing materials, are expensed as incurred. We incurred $885,000 in advertising expense during the year ended December 31, 2015. We had no similar expenses during the years ended December 31, 2014 and 2013, respectively.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. We recognize the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination. A valuation allowance is established when it is more likely than not that the deferred tax assets will not be realized.

Stock-Based Compensation

Stock-based compensation expense is recognized for all share-based payments made to employees, directors and non-employees based on estimated fair values. The fair value of our stock options is calculated using the Black-Scholes option-pricing model which requires judgmental assumptions including volatility, forfeiture rates and expected option life. We use the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period for employees and directors, which is generally the vesting period. Stock options granted to non-employees are accounted for using the fair-value approach and are subject to periodic revaluation over their vesting terms as earned.

Accumulated Other Comprehensive Loss

Accumulated other comprehensive loss is comprised of net loss and certain changes in equity that are excluded from net loss. There was no difference between comprehensive loss and net loss for the years ended December 31, 2015, 2014 or 2013.

Financial Instruments and Concentrations of Credit Risk

Cash and cash equivalents, receivables, accounts payable and accrued liabilities, which are recorded at invoiced amount or cost, approximate fair value based on the short-term nature of these financial instruments. The fair value of short-term investments is based on quoted market prices. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments and receivables. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, our cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, we invest our excess cash in high quality securities such as money market mutual funds, certificates of deposit and commercial paper.

Major Customers

We sell OMIDRIA through a limited number of wholesalers. Each of these wholesalers, together with entities under their common control, accounted for greater than 10% of total revenues for the year ended December 31, 2015 and greater than 10% of accounts receivable as of December 31, 2015 as noted below.

	Percentage of Total Revenue	Percentage of Accounts Receivable
Distributor A	37%	45%
Distributor B	31%	23%
Distributor C	28%	27%

Major Suppliers

We use a small number of contract manufacturers to supply OMIDRIA and to produce clinical trial material which creates a concentration of risk for us. With regards to OMIDRIA, Patheon Manufacturing Services, LLC (Patheon) is completing the analytical testing required before transferring OMIDRIA commercial product, costing $1.3 million, to us. We anticipate receiving the product during the first quarter of 2016 and the product dating will allow the product to be sold through at least the third quarter of 2018. This is the final commercial supply of OMIDRIA that Patheon will be available to produce using Patheon's facility currently approved for manufacturing OMIDRIA.

We have entered into a non-exclusive agreement with Hospira Worldwide, Inc. (Hospira) for the ongoing commercial supply of OMIDRIA and we are currently completing the manufacturing process transfer, process validation and approval of Hospira as a manufacturing site for OMIDRIA. We anticipate Hospira will be able to provide OMIDRIA commercial product to us beginning in 2017.

We believe the commercial supply of OMIDRIA currently undergoing final analytical testing at Patheon plus our OMIDRIA inventory on hand will be adequate to supply our needs of OMIDRIA until Hospira is able to supply our OMIDRIA commercial product needs.

While one source of supply is utilized for OMIDRIA and generally one source for each of our product candidates, other sources are available should we need to change suppliers. We endeavor to maintain reasonable levels of drug supply for our commercial and clinical trial use. A change in suppliers, however, could cause a delay in delivery of OMIDRIA or our clinical trial material that would adversely affect our business.

Recently Adopted Accounting Pronouncements

For the year ended December 31, 2015 we adopted and applied retrospectively Financial Accounting Standards Board (FASB) Accounting Standards Update, or ASU, No. 2015-03, related to simplifying the presentation of debt issuance costs. This standard requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction to the liability. The adoption of ASU 2015-03 resulted in the reclassification of $300,000 of debt issuance costs from Other Current Assets and Other Assets to Current Portion of Notes Payable and Notes Payable in our December 31, 2014 Consolidated Balance Sheet.

In November 2015, FASB issued ASU, No. 2015-17 that simplifies the presentation of deferred tax assets and liabilities by jurisdiction, along with any related valuation allowance. The new guidance requires companies to classify all deferred tax assets and liabilities as noncurrent on the balance sheet. We have elected to apply this standard prospectively for the year ended December 31, 2015. As we have a full valuation allowance against our deferred tax assets for all periods presented, the adoption had no material impact on the presentation of our financial condition, results of operations, cash flow and financial statement disclosures.

Recent Accounting Pronouncements

In February 2016, FASB issued ASU 2016-02 related to lease accounting. This standard requires lessees to recognize a right-of-use asset and a lease liability for most leases. This standard must be applied using a modified retrospective transition and is effective for all annual and interim periods beginning after December 15, 2018. Earlier adoption is permitted. We are evaluating how this new standard will impact the presentation of our financial statements and related disclosures.

In July 2015, FASB issued ASU 2015-11 related to simplifying the measurement of inventory. This standard requires inventory to be measured at the lower of cost or net realizable value. This standard must be applied prospectively and is effective for all annual and interim periods beginning after December 15, 2016. Earlier application is permitted as of the beginning of an interim or annual reporting period. This standard is not expected to have a material impact on the presentation of the our financial position.

In August 2014, FASB issued ASU No. 2014-15 related to disclosure of an entity’s ability to continue as a going concern. This standard requires management to evaluate whether substantial doubt exists regarding the entity’s ability to continue as a going concern at each reporting period for a duration of one year after the date the financial statements are issued or available to be issued. The standard establishes certain required disclosures if substantial doubt exists. This standard must be applied prospectively and is effective for interim and annual periods beginning after December 15, 2016. We will review the impact of the standard upon our disclosures, if applicable, beginning in 2017.

In May 2014, FASB issued ASU No. 2014-09 related to the recognition of revenue that supersedes existing guidance. This standard clarifies the principles for recognizing revenue utilizing a five-step process. This standard must be applied retroactively to each prior reporting period presented, or retrospectively with the cumulative effect of applying the standard recognized in the period adopted. As amended, the standard is effective for interim and annual periods beginning after December 15, 2017 and cannot be adopted before that effective date. We are currently evaluating the impact that this standard may have on our financial statements once it is adopted.

Note 3—Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common share equivalents outstanding for the period, determined using the treasury-stock method.

The basic and diluted net loss per share amounts for the years ended December 31, 2015, 2014 and 2013 were computed based on the shares of common stock outstanding during the respective periods. Potentially dilutive securities excluded from the diluted loss per share calculation are as follows:

	Year Ended December 31,		
	2015	2014	2013
Outstanding options to purchase common stock	8,310,235	8,364,469	6,969,303
Warrants and pre-funded warrants to purchase common stock	749,250	551,435	609,016
Total potentially dilutive securities	9,059,485	8,915,904	7,578,319

Note 4—Cash, Cash Equivalents and Investments

As of December 31, 2015 and 2014, all investments are classified as short-term and available-for-sale on the accompanying Consolidated Balance Sheets. We did not own any securities with unrealized loss positions as of December 31, 2015 or 2014. Investment income, which is included as a component of other income (expense), consists primarily of interest earned.

Note 5—Fair-Value Measurements

On a recurring basis, we measure certain financial assets at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The accounting standard establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available. The following summarizes the three levels of inputs required:

Level 1—Observable inputs for identical assets or liabilities, such as quoted prices in active markets;

Level 2—Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3—Unobservable inputs in which little or no market data exists, therefore they are developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

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

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	$10,679	$—	$—	$10,679
Money-market funds classified as short-term investments	26,898	—	—	26,898
Total	$37,577	$—	$—	$37,577

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	$679	$—	$—	$679
Money-market funds classified as short-term investments	6,532	—	—	6,532
Total	$7,211	$—	$—	$7,211

Cash held in demand deposit accounts of $1.4 million and $354,000 is excluded from our fair-value hierarchy disclosure as of December 31, 2015 and 2014, respectively. There were no unrealized gains and losses associated with our short-term investments as of December 31, 2015 or 2014. The carrying amounts reported in the accompanying

Consolidated Balance

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Sheets for receivables, accounts payable and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

Note 6—Certain Balance Sheet Accounts

Receivables

	December 31, 2015	2014
	(In thousands)	
Trade receivables, net	$6,208	$—
Grant receivables	136	324
Other receivables	173	68
Total receivables	$6,517	$392

Trade accounts receivable are shown net of $191,000 of chargebacks and product return allowances as of December 31, 2015.

Inventory

	December 31, 2015	2014
	(In thousands)	
Raw materials	$93	$—
Work-in-process	158	—
Finished goods	221	568
Total inventory	$472	$568

Property and Equipment

	December 31, 2015	2014
	(In thousands)	
Laboratory equipment	$1,735	$1,636
Office equipment and furniture	625	615
Computer equipment	482	403
Capital lease equipment	367	230
Computer software	174	126
Total cost	3,383	3,010
Less accumulated depreciation and amortization	(2,432)	(2,228)
Total property and equipment, net	$951	$782

For the years ended December 31, 2015, 2014 and 2013, depreciation and amortization expense was $209,000, $317,000 and $302,000, respectively.

Accrued Expenses

	December 31, 2015	2014
	(In thousands)	
Contract research and development	$2,973	$1,280
Employee compensation	2,590	2,421
Consulting and professional fees	2,400	1,952
Clinical trials	1,108	828
Other accruals	681	589
Total accrued liabilities	$9,752	$7,070

Note 7—Notes Payable

Loan and Security Agreement

In October 2010, we entered into a loan and security agreement (the Oxford Loan Agreement) with Oxford Finance LLC (Oxford). In December 2012 we amended the Oxford Loan Agreement and increased the outstanding principal balance to $20.0 million. The Oxford Loan Agreement provided for interest-only payments at an annual rate of 9.25% through December 31, 2013 with principal and interest payments commencing January 1, 2014. In connection with the Oxford Loan Agreement, we agreed to pay Oxford $1.4 million in a loan maturity fee that was being amortized to interest expense using the effective-interest method.

In March 2014, we entered into a Loan and Security Agreement (the Oxford/MidCap Loan Agreement) with Oxford and MidCap Financial SBIC, LP (MidCap) pursuant to which we borrowed $32.0 million. We used $19.1 million of the loan proceeds to repay all of the amounts owed by us under our then outstanding Oxford Loan Agreement from Oxford and, after deducting loan initiation costs, we received $12.7 million in net proceeds. The Oxford/MidCap Loan Agreement provided for interest-only payments at an annual rate of 9.25% through March 1, 2015 with principal and interest payments of $1.0 million commencing April 1, 2015 through its maturity date of March 1, 2018. In addition, the Oxford/MidCap Loan Agreement required a $2.2 million loan maturity fee payment upon full repayment of the loan and a prepayment fee equal to 1.0% of the then-outstanding principal balance if we paid the loan prior to the maturity date.

We accounted for the Oxford/MidCap Loan Agreement as a debt modification and, accordingly, the unamortized debt issuance costs associated with the then-outstanding loan with Oxford, and the debt issuance costs associated with the Oxford/MidCap Loan Agreement were being amortized to interest expense using the effective interest method over the remaining term of Oxford/MidCap Loan Agreement. Additionally, the loan maturity fee, which was treated as a debt discount, was being amortized to interest expense using the effective-interest method.

In December 2015, we entered into a new Loan and Security Agreement (the Oxford/EWB Loan Agreement) with Oxford and East West Bank (EWB) pursuant to which we borrowed $50.0 million. In addition, under the Oxford/EWB Loan Agreement we can borrow an additional $20.0 million in two tranches of $10.0 million each through June 30, 2017, contingent upon the satisfaction of certain conditions including minimum net revenues from OMIDRIA. We used $27.3 million of the loan proceeds to repay all of the amounts owed by us under our then-outstanding Oxford/Midcap Loan Agreement including the outstanding principal of $24.8 million, the loan maturity fee of $2.2 million and the prepayment fee of $248,000. After deducting all loan initiation and outstanding interest on the Oxford/MidCap Loan Agreement, we received $22.3 million in net proceeds. We accounted for the termination of the Oxford/Midcap Loan Agreement as a debt extinguishment and, accordingly, incurred a loss of $1.3 million associated with the unamortized loan maturity fee and the prepayment fee.

The Oxford/EWB Loan Agreement requires monthly interest-only payments of $385,000 on the original $50.0 million we borrowed computed at an annual rate of 9.25% through July 1, 2017. Beginning August 1, 2017, monthly principal and interest payments of approximately $1.9 million are due on the original $50.0 million we borrowed through the maturity date of January 1, 2020. In addition, the Oxford/EWB Loan Agreement requires a $3.8 million loan maturity fee upon full repayment of the initial $50.0 million borrowed and $525,000 for each additional $10.0 million

borrowed. We may prepay the outstanding principal balance in its entirety at any time if we pay a prepayment equal to 1.0% of the then-outstanding principal balance. As security under the Oxford/EWB Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property (other than proceeds derived from any intellectual property).

The Oxford/EWB Loan Agreement contains covenants that require us to maintain $10.0 million in restricted cash and certain eligible term investments, meet an annual OMIDRIA revenue minimum for 2016 and quarterly OMIDRIA revenue minimums in 2017 and 2018, and to establish an at-the-market (ATM) equity facility that we established on January 6, 2016 (see Note 10). The Oxford/EWB Loan Agreement also contains covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, repurchase stock, license our intellectual property for a limited set of our programs without lender approval or pledge our intellectual property. Additionally, the Oxford/EWB Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breaches, occurrence of a material adverse effect (MAE, as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgments, and a change of control. The occurrence of an event of default could result in the acceleration of the Oxford/EWB Loan Agreement and, under certain circumstances, could increase our interest rate by 5.0% per annum during the period of default. MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our inability to repay any portion of the loans in accordance with the terms of the Oxford/EWB Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the enforceability of any material provision of the Oxford/EWB Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce their rights and remedies under the Oxford/EWB Loan Agreement or related agreements.

As of December 31, 2015, the outstanding principal on the Oxford/EWB Loan Agreement was $50.0 million and the remaining unamortized discount and debt issuance costs were $3.8 million and $436,000, respectively. Additionally, there were no covenant violations during the year ended December 31, 2015.

Equipment Financing

We have capital leases for certain lab and office equipment which have lease terms expiring between October 2017 and June 2019. Equipment costs related to these capital leases of $367,000 and $230,000 is included in our property and equipment as of December 31, 2015 and December 31, 2014, respectively and the accumulated depreciation on this equipment was $98,000 and $52,000, respectively. The remaining principal payments under these capital leases totaled $281,000 and $185,000 as of December 31, 2015 and 2014, respectively.

Future Principal Payments

Future principal payments as of December 31, 2015 under the Oxford/EWB Loan Agreement and our capital equipment financing leases, based on stated contractual maturities, are as follows:

Year Ending December 31,	Total
	(In thousands)
2016	$73
2017	7,627
2018	19,432
2019	21,258
2020	1,891
Total future principal payments	$50,281

The principal payments reflected in the table above exclude the $436,000 unamortized balance of the debt discount.

Note 8—Grant Revenue

Revenues recognized from grants are as follows:

	Year Ended December 31,		
	2015	2014	2013
	(In thousands)		
Small Business Innovative Research Grants (SBIR)	$245	$539	$630
Vulcan Inc.	—	—	970
Total revenue	$245	$539	$1,600

We have periodically received Small Business Innovative Research (SBIR) grants from the National Institutes of Health (NIH) which are used to support the research and development of our product candidates. We recorded revenue related to these grants of $245,000, $539,000 and $630,000 for the years ended December 31, 2015, 2014 and 2013, respectively. We recorded cost reductions to property and equipment due to assets being purchased with grant funding of $80,000 for the year ended December 31, 2014. We had no similar cost reductions to property and equipment for the years ended December 31, 2015 and 2013. As of December 31, 2015, $219,000 of potential revenue remained available under these grants, if qualifying research is performed.

In 2010, we entered into a platform development funding agreement with Vulcan Inc. and its affiliate (collectively, Vulcan) pursuant to which we received $20.0 million for our G protein-coupled receptor (GPCR) program. The revenue was recognized as costs were incurred or as a reduction to the costs of assets purchased in direct proportion to the related GPCR expenses. For the year ended December 31, 2013, we recognized all the remaining revenue of $970,000 from this funding agreement.

Note 9—Commitments and Contingencies

Real Estate and Equipment Lease Obligations

We lease office and laboratory spaces in The Omeros Building. The initial term of this lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of December 31, 2015, the remaining aggregate non-cancelable rent under the initial terms of the lease was $54.5 million. The deferred rent balance of $9.2 million relates to rent deferrals and landlord funded lease incentives since the inception of our lease and is being amortized to research and development and selling, general and administrative expense on a straight-line basis through the initial term of the lease.

Rent expense, including the amortization of lease incentives and rent deferrals, totaled $4.5 million, $4.5 million and $4.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

We periodically sublease unused office and laboratory space in The Omeros Building to third-party tenants. Rental income received under these subleases was $889,000, $568,000 and $550,000 for the years ended December 31, 2015, 2014 and 2013, respectively. Rental income is recorded as other income in the accompanying Consolidated Statements of Operations and Comprehensive Loss.

We rent equipment under various operating lease agreements which have remaining aggregate non-cancellable rent of $76,000 at December 31, 2015.

Future minimum payments related to these leases and The Omeros Building lease, which exclude common area maintenance and related operating expenses, at December 31, 2015, are as follows:

Year Ending December 31,	Lease Payments	Sublease Receipt	Net Lease Payments
	(In thousands)		
2016	$4,106	$682	$3,424
2017	4,188	580	3,608
2018	4,259	—	4,259
2019	4,350	—	4,350
2020	4,450	—	4,450
Thereafter	33,263	—	33,263
Total	$54,616	$1,262	$53,354

Contracts

As of December 31, 2015, we have a firm purchase commitment with Patheon for the manufacture of $1.3 million of commercial supply of OMIDRIA. We anticipate receiving the product during the first quarter of 2016.

Development Milestones and Product Royalties

Phosphodiesterase 10 (PDE10) inhibitors - In connection with a funding agreement with The Stanley Medical Research Institute entered into in December 2006, beginning the first calendar year after commercial sales of any therapeutic product that inhibits or modulates PDE10 (including for schizophrenia or Huntington's disease), we are obligated to pay royalties based on net income of the product, as defined in the agreement. Based on the amount of grant funding received, the maximum amount of royalties payable by us is $12.8 million. For the years ended December 31, 2015, 2014 and 2013, we did not owe any royalties.

Peroxisome proliferators activated receptor gamma (PPAR) - In February 2009, we entered into a patent assignment agreement whereby we acquired all intellectual property rights, including patent applications, related to PPAR agonists for the treatment and prevention of addictions to substances of abuse, as well as other compulsive behaviors. In February 2011, we amended the patent assignment agreement to include all intellectual property rights, including patent applications, related to dietary supplements that increase PPAR activity. We will be required to make payments up to $3.8 million in total, for both PPAR agonists and dietary supplements that increase PPAR activity, upon achievement of certain development events, such as the initiation of clinical trials and receipt of marketing approval. In addition, we are obligated to pay a low single-digit percentage royalty on any net sales of drug products that are covered by the patent assignment agreement. For the years ended December 31, 2015, 2014 and 2013, we did not owe any development milestones or royalties.

Phosphodiesterase 7 (PDE7) inhibitors - Under a license agreement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) we hold an exclusive license to phosphodiesterase 7 (PDE7) inhibitors owned by Daiichi Sankyo for use in (1) the treatment of movement disorders and other specified indications; (2) addiction and compulsive disorders; and (3) all other indications except those related to dermatologic conditions. We will be required to make milestone payments to Daiichi Sankyo of up to $33.5 million upon the achievement of certain events, such as successful completion of certain preclinical toxicology studies; dosing of human subjects in Phase 1, 2 and 3 clinical trials; receipt of marketing approval of a PDE7 inhibitor product; and reaching specified sales milestones. However, if only one of the three indications is advanced through each milestone, the total milestone payments would be $23.5 million. In addition, we are obligated to pay Daiichi Sankyo a low single-digit percentage royalty on any net sales of a PDE7 inhibitor licensed under the agreement provided that if the sales are made by a sublicensee, the amount payable by us to Daiichi Sankyo is capped at a low double-digit percentage of all royalty and specified milestone payments that we receive from the sublicensee. For the year ended December 31, 2013, we paid $50,000 upon execution of an amendment which was recognized as research and development expense. For the years ended December 31, 2015, 2014 and 2013, we did not owe any development milestones or royalties.

Mannan-binding lectin-associated serine protease-2 (MASP-2) - In April 2010, we entered into an exclusive license agreement with Helion Biotech ApS (Helion), pursuant to which we received a royalty bearing, worldwide exclusive license to all of Helion's intellectual property rights related to MASP-2 antibodies, polypeptides and methods in the field of inhibition of mannan-binding lectin-mediated activation of the complement system for the prevention, treatment or diagnosis of any disease

or condition. We will be required to make development and sales milestone payments to Helion of up to $6.1 million upon the achievement of certain events, such as the filing of an Investigational New Drug Application (IND) with the FDA; initiation of Phase 2 and 3 clinical trials; receipt of marketing approval; and reaching specified sales milestones. We are obligated to pay Helion a low single-digit percentage royalty on net sales of a MASP-2 inhibitor product covered by the patents licensed under the agreement. For the year ended December 31, 2015, we did not owe any development milestones or royalties. For the years ended December 31, 2014 and 2013, we incurred development milestone costs of $300,000 and $200,000, respectively, under this agreement which was recognized as research and development expense.

G protein-coupled receptor (GPCR) - In connection with our funding agreements with Vulcan and LSDF discussed in Note 8, we agreed to pay Vulcan and LSDF tiered percentages of the net proceeds derived from the GPCR program. The percentage rates decrease as the cumulative net proceeds reach specified thresholds, and the blended percentage rate in the aggregate is in the mid-teens with respect to approximately the first $1.5 billion of cumulative net proceeds. If we receive cumulative net proceeds in excess of approximately $1.5 billion, the percentage rate decreases to one percent. Pursuant to the agreement with Vulcan, we may pay a portion of Vulcan's share of the one percent of net proceeds to a life sciences initiative (LSI) to be established in accordance with the LSDF agreement. The LSI will be a non-profit, tax-exempt organization with a mission to advance life sciences in the State of Washington.

Net proceeds are generally defined in the Vulcan and LSDF agreements as (1) all consideration received by us in any form relating directly to the GPCR program less (2) all expenses and expenditures in excess of $25.0 million incurred by us in connection with the GPCR program. Any consideration that we receive (a) from government entities (subject to specified exceptions), (b) from third parties that have designated such consideration for the purpose of funding research and development expenses and related overhead or (c) in the form of grants, as well as any expenses or expenditures that we incur that are paid for with such consideration, are excluded for purposes of determining net proceeds.

Under our agreement with Vulcan, we granted Vulcan a security interest in our personal property related to the GPCR program, other than intellectual property, which security interest is junior to any existing or future security interests granted in connection with a financing transaction and which will be automatically released after Vulcan receives $25.0 million under the agreement. We also agreed not to grant any liens on intellectual property related to the GPCR program. The term of our agreement with Vulcan is 35 years, provided that the term will automatically extend until the cumulative net proceeds that we receive from the GPCR program are approximately $1.5 billion.

Under our agreement with LSDF, after LSDF receives $25.0 million, any remaining amounts that would be payable to LSDF will be paid to LSI. Our obligations with respect to LSI are limited to creating LSI's charter documents, incorporating LSI, selecting directors and applying for tax exempt status, all in consultation with LSDF. The term of our agreement with LSDF expires on the six-month anniversary following the last date that we deliver a report related to our incurrence of grant-funded expenses described in the agreement. The term of our payment obligations to LSDF is the same as that under our agreement with Vulcan.

As of December 31, 2015, we have not derived any net proceeds as defined in the Vulcan and LSDF agreements from our GPCR program.

Litigation

In July 2015, we received a Notice Letter from Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC, (collectively, Par) stating that Par filed an Abbreviated New Drug Application (ANDA) containing a Paragraph IV Certification under the Hatch-Waxman Act seeking approval from the FDA to market a generic version of OMIDRIA prior to the expiration of three patents listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for OMIDRIA (the Orange Book Patents). Following receipt of the Paragraph IV Notice Letter, in September 2015 we filed a patent infringement lawsuit under the Hatch-Waxman Act against Par in the U.S. District Court for the District of New Jersey and in the U.S. District Court for the District of Delaware. Based on our decision to pursue the action in federal court in Delaware, we voluntarily dismissed the complaint filed in the U.S. District Court for the District of New Jersey. The complaint that we filed in the U.S. District Court for the District of Delaware has been served on Par and Par has filed an answer asserting defenses and counterclaims for declaratory

judgment of patent invalidity and non-infringement. We intend to seek leave to amend the lawsuit to assert a fourth patent, that issued after Par's Notice Letter, and which was granted by the U.S. Patent and Trademark Office (USPTO) after the USPTO considered all alleged prior art that was identified by Par in its Paragraph IV Notice Letter. The filing of suit against Par triggered a 30-month stay of the FDA's approval of Par's ANDA, which is expected to remain in effect until late January 2018. We have reviewed the assertions in Par's Paragraph IV Notice Letter and believe they do not have merit, and we intend to prosecute vigorously our patent infringement claims against Par.

In connection with an administrative review by NIH of the grants that were the subject of the Klein lawsuit, we reimbursed the NIH $1.1 million in October 2013. The payment was recorded as selling, general and administrative expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss.

In October 2013, we and our chief executive officer entered into a settlement agreement with our former insurer related to our former insurer's defense of, and coverage obligations related to, the Klein lawsuit. Per the settlement agreement, we received $12.5 million in October 2013 which we recorded as litigation settlement in the accompanying Consolidated Statements of Operation and Comprehensive Loss. We considered this particular litigation settlement an infrequent item given the nature of the lawsuit and have included the settlement as a separate component of non-operating income.

Note 10—Shareholders' Equity

Common Stock

As of December 31, 2015, we had reserved shares of common stock for the following purposes:

Options granted and outstanding	8,310,235
Options available for future grant	1,724,987
Common stock warrants	749,250
Total shares reserved	10,784,472

Options Available for Future Grant - On January 1, 2016, an additional 1,785,714 shares became available for future issuance under the 2008 Equity Incentive Plan (the 2008 Plan) in accordance with the annual increase provisions of the 2008 Plan. These additional shares are not included in the table above.

At Market Issuance Sales Agreement - In January 2016, we entered into an At Market Issuance Sales Agreement (the ATM Agreement) with JonesTrading Institutional Services LLC (JonesTrading) pursuant to which we may direct JonesTrading to sell shares of our common stock with an aggregate offering price of up to $100 million directly on The Nasdaq Global Market, through a market maker other than on an exchange or in negotiated transactions. Any sales made under the ATM Agreement are based solely on our instructions and JonesTrading will receive a 1.7% commission from the gross proceeds. The ATM Agreement may be terminated by either party at any time upon 10 days' notice to the other party or by JonesTrading at any time in certain circumstances including the occurrence of a material adverse effect to Omeros.

Securities Offerings - In February 2015, we sold 3.4 million shares of our common stock at a public offering price of $20.03 and sold pre-funded warrants to purchase up to 749,250 shares of our common stock at a public offering price of $20.02 per pre-funded warrant share. The public offering price for the pre-funded warrants was equal to the public offering price of the common stock, less the $0.01 per share exercise price of each pre-funded warrant. After deducting underwriter discounts and offering expenses of $4.9 million, we received net proceeds from the transaction of $79.1 million.

In March 2014, we sold 3.5 million shares of our common stock at a public offering price of $11.50 per share. After deducting underwriter discounts and offering expenses of $2.5 million, we received net proceeds from the transaction of $37.8 million.

In October 2013, we sold 374,000 shares of our common stock with a weighted average price of $13.29 per share under an at-the-market sales agreement and received $4.9 million in net proceeds. The agreement expired in April 2014.

In May 2013, we sold 3.9 million shares of our common stock at a price of $4.14 per share in a registered direct offering. After deducting offering expenses of $39,000, we received net proceeds from the transaction of $16.1 million.

Warrants

The following table summarizes our outstanding pre-funded warrants at December 31, 2015, which have an exercise price of $0.01:

Outstanding At December 31, 2015	Expiration Date	Exercise Price
749,250	February 2, 2022	$0.01

In March 2009, we issued warrants with an exercise price of $12.25 per share to brokers who assisted us in our Series E financing (the Series E Warrants). In March 2013, we extended the expiration dates of the Series E Warrants by one year and in each of March 2014 and September 2014 we extended their expiration by six months. We evaluated the fair value of the Series E Warrants before and after each modification, and we recorded $863,000 and $41,000 change in fair value as other expense in

the accompanying Consolidated Statement of Operations and Comprehensive Loss for the years ended December 31, 2014 and 2013, respectively.

For the year ending December 31, 2014, Series E Warrants were exercised, through cash and cashless net exercise, resulting in cash proceeds of $68,000 and the issuance of 28,653 shares of our common stock. Additionally, for the year ended December 31, 2015, we received cash proceeds of $1.4 million upon the cash and cashless exercise of Series E Warrants which resulted in the issuance of 133,240 shares of our common stock.

Note 11—Stock-Based Compensation

The 2008 Plan provides for the grant of incentive and non-statutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, directors and consultants and subsidiary corporations' employees and consultants. Options are granted with exercise prices equal to the closing fair market value of the common stock on the date of the grant. The terms of options may not exceed 10 years and options generally vest over a four-year period.

The 2008 Plan also allows any shares returned under our Amended and Restated 1998 Stock Option Plan (the 1998 Plan), as a result of cancellation of options or repurchase of shares issued pursuant to the 1998 Plan, to be issued under the 2008 Plan. In addition, the 2008 Plan provides for annual increases in the number of shares available for issuance thereunder on the first day of each year, equal to the lower of:

- five percent of the outstanding shares of our common stock on the last day of the preceding year;
- 1,785,714 shares; or
- such other amount as our board of directors may determine.

As of December 31, 2015, a total of 10,035,222 shares were reserved for issuance under our stock plans, of which 1,724,987 were available for future grants. On January 1, 2016, an additional 1,785,714 shares became available for future issuance under our 2008 Plan in accordance with the annual increase. In February 2016, approximately 1.3 million shares were granted to employees related to annual performance grants.

Compensation cost for stock options granted to employees and directors is based on the grant-date fair value and is recognized over the vesting period of the applicable option on a straight-line basis. Stock-based compensation expense is based on options ultimately expected to vest, and therefore has been reduced for estimated forfeitures. We estimate forfeitures based on our historical experience; separate groups of employees that have similar historical forfeiture behavior are considered separately for expense recognition.

The fair value of each option grant to employees and directors is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were applied to employee & director stock option grants during the periods ended:

	Year Ended December 31,		
	2015	2014	2013
Estimated weighted-average fair value	$11.31	$7.39	$6.87
Weighted-average assumptions:			
Expected volatility	71 %	73 %	88 %
Expected term, in years	6.0	5.8	5.8
Risk-free interest rate	1.68 %	1.87 %	1.66 %
Expected dividend yield	— %	— %	— %

(A) Expected Volatility. Prior to October 14, 2014 the expected volatility rate used to value stock option grants was based on volatilities of a peer group of similar companies whose share prices were publicly available due to our limited trading history. The peer group was developed based on companies in the pharmaceutical and biotechnology industry in a similar stage of development. As of October 2014, we determined it was appropriate to rely 100% on our own historical realized volatility given our own trading history was roughly equivalent to the average expected term of our options and we do not anticipate future volatility will differ significantly from the past. This change in estimate did not have a material impact on our operating income, net income or earnings per share.

(B)

Expected Term. We elected to utilize the “simplified” method for “plain vanilla” options to determine the expected term of our stock option grants. We will continue to use the simplified method until we have sufficient historical data necessary to provide a reasonable estimate of expected life based on the exercise behavior of our option holders. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

(C) Risk-free Interest Rate. The risk-free interest rate assumption was based on zero-coupon U.S. Treasury instruments that had terms consistent with the expected term of our stock option grants.

(D) Expected Dividend Yield. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future.

Stock options granted to non-employees are accounted for using the fair-value approach. The fair value of non-employee option grants is estimated using the Black-Scholes option-pricing model and are re-measured over the vesting term as earned. The estimated fair value is charged to expense over the applicable service period. During the years ended December 31, 2015, 2014 and 2013, we granted to non-employees options to purchase 4,200 shares, 86,000 shares and 40,000 shares of common stock, respectively.

Stock-based compensation expense includes amortization of stock options granted to employees and non-employees and has been reported in our Consolidated Statements of Operations and Comprehensive Loss as follows:

	Year Ended December 31,		
	2015	2014	2013
	(In thousands)		
Research and development	$4,977	$4,754	$3,588
Selling, general and administrative	4,604	4,164	2,664
Total stock-based compensation expense	$9,581	$8,918	$6,252

In connection with the non-employee options, we recognized expense of $492,000, $289,000 and $71,000 during the years ended December 31, 2015, 2014 and 2013, respectively.

Stock option activity for all stock plans is as follows:

	Options Outstanding	Weighted-Average Exercise Price per Share	Remaining Contractual Life (in years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2014	8,364,469	$7.52		
Granted	350,975	17.90		
Exercised	(277,356)	5.13		
Forfeited and expired	(127,853)	12.36		
Balance at December 31, 2015	8,310,235	$7.97	6.07	$ 65,610
Vested and expected to vest at December 31, 2015	8,096,339	$7.85	6.00	$ 64,731
Exercisable at December 31, 2015	6,217,364	$6.61	5.24	$ 56,757

The total intrinsic value of options exercised during the years ended December 31, 2015, 2014 and 2013 was $3.9 million, $2.9 million and $1.1 million, respectively.

Information about stock options outstanding and exercisable is as follows:

	December 31, 2015				
	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number of Options	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price	Number of Options	Weighted-Average Exercise Price
$0.98-$4.09	1,434,412	1.07	$1.17	1,434,412	$1.17
$4.10-$8.00	1,975,794	5.12	5.25	1,958,011	5.23
$8.01-$11.42	2,735,818	7.17	9.79	2,063,009	9.81
$11.43-$25.00	2,164,211	8.86	12.66	761,932	11.73
$0.98-$25.00	8,310,235	6.07	$7.97	6,217,364	$6.61

At December 31, 2015, there were 2,092,871 unvested options outstanding that will vest over a weighted-average period of 2.1 years. Excluding non-employee stock options, the remaining estimated compensation expense to be recognized in connection with these options is $12.9 million.

Note 12—Income Taxes

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

	December 31, 2015	2014
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$110,092	$88,399
Tax credit carryforwards	14,758	9,569
Stock-based compensation	8,136	5,511
Deferred rent	3,324	3,077
Other	2,744	2,084
Total deferred tax assets	139,054	108,640
Less valuation allowance	(139,054)	(108,640)
Net deferred tax assets	$—	$—

As of December 31, 2015 and 2014, we had Federal net operating loss carryforwards of approximately $325.9 million and $264.1 million, respectively, state net operating losses of approximately $30.6 million and $100,000, respectively, and tax credit carryforwards of approximately $14.8 million and $9.6 million, respectively. Approximately $5.9 million of our net operating loss carryforwards relate to tax deductible stock-based compensation in excess of amounts recognized for financial statement purposes. To the extent that net operating loss carryforwards, if realized, relate to stock-based compensation, the resulting tax benefits will be recorded to shareholders' equity, rather than to the results of operations.

In certain circumstances, due to ownership changes, our net operating loss and tax credit carryforwards may be subject to limitations under Section 382 of the Internal Revenue Code. To date, we have not completed a Section 382 study. Unless previously utilized, our net operating loss and research and development tax credit carryforwards expire between 2018 and 2035.

We have established a 100% valuation allowance due to the uncertainty of our ability to generate sufficient taxable income to realize the deferred tax assets. Our valuation allowance increased $30.4 million, $25.8 million and $14.5 million in 2015, 2014 and 2013, respectively, primarily due to net operating losses incurred during these periods.
Reconciliation of income tax computed at Federal statutory rates to the reported provisions for income taxes is as follows:

	Year ended December 31,		
	2015	2014	2013
Federal statutory tax rate	(34)%	(34)%	(34)%
State tax rates	(2)%	— %	— %
Other permanent differences	1 %	2 %	3 %
Change in valuation allowance	41 %	35 %	36 %
Tax credits	(5)%	(4)%	(5)%
Other	(1)%	1 %	— %
Effective tax rate	— %	— %	— %

We file Federal and state income tax returns, which provides varying statutes of limitations on assessments. However, because of net operating loss carryforwards, substantially all of our tax years remain open to federal and state tax examination.
The guidance for accounting for uncertainties in income taxes requires that we recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As of December 31, 2015, 2014 and 2013, we maintained an uncertain tax position of $212,000 related to a reduction of our research and development credit deferred tax asset. Further, there were no unrecognized tax benefits that, if recognized, would impact our effective tax rate.
We recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense. To date, there have been no interest or penalties charged to us in relation to the underpayment of income taxes.

Note 13—401(k) Retirement Plan
We have adopted a 401(k) plan. To date, we have not matched employee contributions to the plan. All employees are eligible to participate, provided they meet the requirements of the plan.

Note 14—Quarterly Information (Unaudited)

The following table summarizes the unaudited statements of operations and comprehensive loss for each quarter of 2015 and 2014 (in thousands, except per share amounts):

2015	For the Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenue	$388	$3,187	$3,259	$6,675
Total operating expenses	18,318	19,154	22,560	24,715
Loss from operations	(17,930)	(15,967)	(19,301)	(18,040)
Net loss	(18,669)	(16,680)	(19,921)	(19,826)
Basic and diluted net loss per share	$(0.51)	$(0.44)	$(0.53)	$(0.52)

2014	For the Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenue	$100	$45	$214	$180
Total operating expenses	15,784	17,262	17,346	20,155
Loss from operations	(15,684)	(17,217)	(17,132)	(19,975)
Net loss	(16,642)	(17,991)	(18,327)	(20,713)
Basic and diluted net loss per share	$(0.54)	$(0.53)	$(0.54)	$(0.61)

EXHIBIT INDEX

Exhibit No.	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit No.	Filing Date	
3.1	Amended and Restated Articles of Incorporation of Omeros Corporation	10-K	001-34475	3.1	03/31/2010	
3.2	Amended and Restated Bylaws of Omeros Corporation	10-K	001-34475	3.2	03/31/2010	
4.1	Form of Omeros Corporation common stock certificate	S-1/A	333-148572	4.1	10/02/2009	
4.2	Form of Omeros Corporation Pre-Funded Warrant to Purchase Common Stock	8-K	001-34475	4.1	02/02/2015	
10.1*	Form of Indemnification Agreement entered into between Omeros Corporation and its directors and officers	S-1	333-148572	10.1	01/09/2008	
10.2*	Second Amended and Restated 1998 Stock Option Plan	S-1	333-148572	10.2	01/09/2008	
10.3*	Form of Stock Option Agreement under the Second Amended and Restated 1998 Stock Option Plan (that does not permit early exercise)	S-1	333-148572	10.3	01/09/2008	
10.4*	nura, inc. 2003 Stock Plan	S-1	333-148572	10.6	01/09/2008	
10.5*	Form of Stock Option Agreement under the nura, inc. 2003 Stock Plan	S-1	333-148572	10.7	01/09/2008	
10.6*	2008 Equity Incentive Plan	S-1/A	333-148572	10.8	04/01/2008	
10.7*	Form of Stock Option Award Agreement under the 2008 Equity Incentive Plan	10-Q	001-34475	10.2	11/07/2013	
10.8*	Second Amended and Restated Employment Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated April 7, 2010	8-K	001-34475	10.1	04/12/2010	
10.9*	Offer Letter between Omeros Corporation and Marcia S. Kelbon, Esq. dated August 16, 2001	S-1	333-148572	10.12	01/09/2008	
10.10*	Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated June 16, 1994	S-1	333-148572	10.14	01/09/2008	

10.11	Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated June 16, 1994	S-1	333-148572	10.15	01/09/2008
10.12*	Second Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated December 11, 2001	S-1	333-148572	10.16	01/09/2008
10.13	Second Technology Transfer Agreement between Omeros Corporation and Pamela Pierce, M.D., Ph.D. dated March 22, 2002	S-1	333-148572	10.17	01/09/2008
10.14*	Technology Transfer Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated June 16, 1994 (related to tendon splice technology)	S-1	333-148572	10.18	01/09/2008
10.15	Lease dated January 27, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	8-K	001-34475	10.1	02/01/2012

10.16	First Amendment to Lease dated November 5, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.2	11/09/2012
10.17	Second Amendment to Lease dated November 16, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.18	03/18/2013
10.18	Third Amendment to Lease dated October 16, 2013 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.18	03/13/2014
10.19	Fourth Amendment to Lease dated September 8, 2015 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.3	11/09/2015
10.20†	Commercial Supply Agreement between Omeros Corporation and Hospira Worldwide, Inc. dated October 9, 2007	S-1/A	333-148572	10.28	09/16/2009
10.21†	Exclusive License and Sponsored Research Agreement between Omeros Corporation and the University of Leicester dated June 10, 2004	S-1/A	333-148572	10.29	09/16/2009
10.22†	Research and Development Agreement First Amendment between Omeros Corporation and the University of Leicester dated October 1, 2005	S-1	333-148572	10.30	01/09/2008
10.23†	Research and Development Agreement Eighth and Ninth Amendments between Omeros Corporation and the University of Leicester dated March 21, 2012 and September 1, 2013	10-K	001-34475	10.24	03/16/2015
10.24†	Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005	S-1/A	333-148572	10.31	09/16/2009
10.25†	Amendment dated May 8, 2007 to Exclusive License and Sponsored Research Agreement between Omeros Corporation and the Medical Research Council dated October 31, 2005	S-1	333-148572	10.32	01/09/2008
10.26†	Funding Agreement between Omeros Corporation and The Stanley Medical Research Institute dated December 18, 2006	S-1/A	333-148572	10.33	05/15/2009
10.27†	Patent Assignment Agreement between Omeros Corporation and Roberto Ciccocioppo, Ph.D. dated February 23, 2009	S-1/A	333-148572	10.47	09/16/2009

10.28†	First Amendment to Patent Assignment Agreement between Omeros Corporation and Roberto Ciccocioppo, Ph.D. effective December 31, 2010	10-K	001-34475	10.28	03/18/2013
10.29*	Omeros Corporation Non-Employee Director Compensation Policy	S-1/A	333-148572	10.50	09/16/2009
10.30†	License Agreement between Omeros Corporation and Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.) dated March 3, 2010	10-Q	001-34475	10.1	05/12/2010
10.31†	Amendment No. 1 to License Agreement with an effective date of January 5, 2011 between Omeros Corporation and Daiichi Sankyo Co., Ltd.	10-Q	001-34475	10.1	05/10/2011
10.32†	Amendment No. 2 to License Agreement with an effective date of January 25, 2013 between Omeros Corporation and Daiichi Sankyo Co., Ltd.	10-Q	001-34475	10.1	05/09/2013

10.33†	Exclusive License Agreement between Omeros Corporation and Helion Biotech ApS dated April 20, 2010	10-Q	001-34475	10.2	08/10/2010	
10.34†	Platform Development Funding Agreement between Omeros Corporation and Vulcan Inc. and its affiliate dated October 21, 2010	10-K	001-34475	10.44	03/15/2011	
10.35†	Grant Award Agreement between Omeros Corporation and the Life Sciences Discovery Fund Authority dated October 21, 2010	10-K	001-34475	10.45	03/15/2011	
10.36†	Pharmaceutical Manufacturing and Supply Agreement dated March 5, 2014 by and between Patheon Manufacturing Services, LLC (successor-in-interest to DSM Pharmaceuticals, Inc.) and Omeros Corporation	10-Q	001-34475	10.5	05/12/2014	
10.37†	First Amendment to Pharmaceutical Manufacturing and Supply Agreement between Patheon Manufacturing Services (successor-in-interest to DSM Pharmaceuticals, Inc.) and Omeros Corporation dated July 7, 2015	10-Q	001-34475	10.2	11/09/2015	
10.38†	Master Services Agreement between Omeros Corporation and Ventiv Commercial Services, LLC, made as of May 12, 2014	10-Q	001-34475	10.1	08/11/2014	
10.39†	Project Agreement (Detailing and Sales Operation Services) between Omeros Corporation and Ventiv Commercial Services, LLC, made as of May 12, 2014	10-Q	001-34475	10.2	08/11/2014	
10.40	First Amendment to Project Agreement (Detailing and Sales Operation Services) between Omeros Corporation and Ventiv Commercial Services, LLC, dated June 13, 2014	10-Q	001-34475	10.3	08/11/2014	
10.41†	Second Amendment to Project Agreement (Detailing and Sales Operation Services) between Omeros Corporation and Ventiv Commercial Services, LLC, made as of October 17, 2014	10-K	001-34475	10.45	03/16/2015	
10.42	Project Agreement (Sales Operation Services for Client Sales Teams) between Omeros Corporation and Ventiv Commercial Services, LLC, made as of January 1, 2016					X
10.43†	Commercial Supply Agreement among Omeros Corporation, Hospira S.p.A. and Hospira Worldwide, Inc. dated October 3, 2014	10-K	001-34475	10.46	03/16/2015	
10.44†		10-Q	001-34475	10.1	11/09/2015	

	First Amendment to Commercial Supply Agreement dated August 1, 2015 by and between Omeros Corporation and Hospira Worldwide, Inc.					
10.45†	License Agreement effective as of June 9, 2015 by and between Omeros Corporation, JCB Laboratories, LLC, and Fagron Compounding Services, LLC, d/b/a Fagron Sterile Services	10-Q	001-34475	10.1	08/10/2015	
10.46	At Market Issuance Sales Agreement dated January 6, 2016 between Omeros Corporation and JonesTrading Institutional Services LLC	8-K	001-34475	1.1	01/06/2016	
10.47	Loan and Security Agreement between Omeros and Oxford Finance LLC, as collateral agent and as a lender, and East West Bank, as a lender, dated December 30, 2015	8-K	001-34475	10.1	01/06/2016	
10.48	Form of Secured Promissory Note issued by Omeros to Oxford Finance LLC and to East West Bank, each dated December 30, 2015	8-K	001-34475	10.2	01/06/2016	
12.1	Ratio of Earnings to Fixed Charges					X

23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
99.1	Description of Capital Stock	10-K	001-34475	99.1	03/16/2015	
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

* Indicates management contract or compensatory plan or arrangement.
† Portions of this exhibit are redacted in accordance with a grant of confidential treatment.
†† Portions of this exhibit are redacted in accordance with a request for confidential treatment.