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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**91-1663741**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
201 Elliott Avenue West Seattle, Washington	**98119**
(Address of principal executive offices)	**(Zip Code)**

(206) 676-5000
(Registrant's telephone number, including area code)

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 ☒ No ☐

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (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 ☒

As of November 3, 2015, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 37,969,429.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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," "should," "will," "would," and 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% in the U.S. and for sales, marketing and distribution in the European Union and other international territories;*
- *our revenues and our estimate regarding how long our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes;*
- *our ability to raise additional capital through the capital markets 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;*
- *our expectations about the commercial competition that Omidria and our product candidates may face;*
- *our expectations regarding our exclusive license agreement related to OMS103 including, without limitation, manufacturing and commercialization of OMS103 and the commencement and subsequent continuation of product sales on which we will receive royalty revenue;*
- *our expectation that the OMIDRIAssure™ Reimbursement Services Program will increase patient access to Omidria;*
- *our plans for directly hiring sales representatives currently contracted through Ventiv Commercial Services, LLC and our expectations regarding resultant cost impacts;*
- *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;*
- *our ability to design and successfully complete clinical trials and other studies for our products and product candidates, including our Phase 2 clinical trials for OMS721 and 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; and*
- *our expected financial position, performance, revenues, growth, expenses, magnitude of net losses and 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 II of this Quarterly Report on Form 10-Q 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 anticipated developments may not be realized or, even if substantially realized, 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 Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q 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.

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FORM 10-Q FOR THE QUARTER ENDED September 30, 2015

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

OMEROS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)
(unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 601	$ 354
Short-term investments	34,398	6,532
Receivables	2,510	392
Inventory	445	568
Prepaid expense	1,410	1,191
Other current assets	99	120
Total current assets	39,463	9,157
Property and equipment, net	808	782
Restricted cash	679	679
Other assets	467	472
Total assets	$ 41,417	$ 11,090
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 4,575	$ 4,915
Accrued expenses	8,121	7,070
Current portion of notes payable, net of discount	9,577	6,446
Total current liabilities	22,273	18,431
Notes payable, net of current portion and discount	18,974	26,263
Deferred rent	9,174	9,050
Commitments and contingencies (Note 7)		
Shareholders' equity:		
Preferred stock, par value $0.01 per share, 20,000,000 authorized; none issued and outstanding at September 30, 2015 and December 31, 2014	—	—
Common stock, par value $0.01 per share, 150,000,000 authorized; 37,969,429 and 34,185,464 issued and outstanding at September 30, 2015 and December 31, 2014, respectively	380	342
Additional paid-in capital	373,932	285,050
Accumulated deficit	(383,316)	(328,046)
Total shareholders' equity (deficit)	(9,004)	(42,654)
Total liabilities and shareholders' equity	$ 41,417	$ 11,090

See notes to consolidated financial statements

OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues				
Product sales, net	$ 3,244	$ —	$ 6,607	$ —
Grant revenue	15	214	227	359
Total revenue	3,259	214	6,834	359
Costs and expenses:				
Cost of product sales	248	—	624	—
Research and development	13,264	11,772	33,482	36,196
Selling, general and administrative	9,048	5,574	25,926	14,196
Total costs and expenses	22,560	17,346	60,032	50,392
Loss from operations	(19,301)	(17,132)	(53,198)	(50,033)
Interest expense	(871)	(944)	(2,765)	(2,555)
Investment income and other income (expense), net	251	(251)	693	(372)
Net loss	$ (19,921)	$ (18,327)	$ (55,270)	$ (52,960)
Comprehensive loss	$ (19,921)	$ (18,327)	$ (55,270)	$ (52,960)
Basic and diluted net loss per share	$ (0.53)	$ (0.54)	$ (1.48)	$ (1.61)
Weighted-average shares used to compute basic and diluted net loss per share	37,923,353	34,005,642	37,417,915	32,945,346

See notes to consolidated financial statements

OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2015	**2014**
Operating activities:		
Net loss	$ (55,270)	$ (52,960)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of assets	—	(9)
Depreciation and amortization	161	246
Stock-based compensation expense	7,273	5,083
Non-cash interest expense	659	532
Warrant modification expense	—	863
Changes in operating assets and liabilities:		
Receivables	(2,118)	(2)
Prepaid expenses, inventory and other current and noncurrent assets	(159)	(842)
Accounts payable, accrued expenses and other	721	3,949
Deferred rent	124	787
Net cash used in operating activities	(48,609)	(42,353)
Investing activities:		
Purchases of property and equipment, net	(187)	(12)
Purchases of investments	(79,416)	(58,847)
Proceeds from the sale and maturities of investments	51,550	50,534
Net cash used in investing activities	(28,053)	(8,325)
Financing activities:		
Proceeds from issuance of common stock and pre-funded warrants, net of offering costs	79,076	37,754
Net proceeds from borrowings under notes payable	—	12,699
Principal payments on notes payable	(4,738)	(1,464)
Proceeds upon exercise of stock options and warrants	2,571	1,055
Net cash provided by financing activities	76,909	50,044
Net increase (decrease) in cash and cash equivalents	247	(634)
Cash and cash equivalents at beginning of period	354	1,384
Cash and cash equivalents at end of period	$ 601	$ 750
Supplemental cash flow information		
Cash paid for interest	$ 2,141	$ 1,931
Reduction of equipment cost basis due to assets purchased with grant funding	$ —	$ 40

See notes to consolidated financial statements

OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

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 commenced a controlled launch of Omidria to a small number of ambulatory surgery centers (ASCs) in the U.S. in February 2015. In April 2015, we initiated the broad U.S. launch of Omidria and began selling Omidria through wholesalers.

Basis of Presentation

Our condensed consolidated financial statements include the financial position and results of operations of Omeros Corporation and our wholly owned subsidiaries. All inter-company transactions have been eliminated. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of September 30, 2015 and for the three and nine months ended September 30, 2015 and 2014 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2014 has been derived from our audited financial statements but does not include all of the information and footnotes required by GAAP.

The accompanying unaudited condensed consolidated financial statements and notes to condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto that are included in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the U.S. Securities and Exchange Commission (SEC) on March 16, 2015.

Revenue Recognition

Our revenues are comprised of product sales of Omidria and amounts earned for services under grants from the National Institutes of Health (NIH). 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. We record Omidria product revenue upon delivery to our wholesalers or upon shipment to the ASC or hospital for direct sales. 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, distribution fees and estimated product returns utilizing a variety of information, including our historical and projected payer mix, our historical experience as well as industry averages, sale-through and inventory on hand information received directly from wholesalers, changes in the overall marketplace, and the remaining shelf life of product we have previously sold. Accruals are established for these deductions when revenue is recognized, and actual amounts incurred are offset against the applicable accruals. 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.

Product Sales, Net

Chargebacks and Rebates. We have 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 (PHSA) to receive discounts on their qualified purchases of Omidria. We have also entered into a Federal Supply Schedule (FSS) agreement under which certain U.S. government purchasers receive a discount on eligible purchases of Omidria. Under these agreements, our wholesalers forward a chargeback to us for the difference between wholesale acquisition cost (WAC) and the applicable discounted price. We identify the entities that purchase Omidria and which are eligible for FSS or PHSA pricing and, utilizing our historical chargeback information and projected payer mix, we record estimated chargebacks for these entities at the time of sale.

We have entered into a Medicaid Drug Rebate Agreement with the Centers for Medicare & Medicaid Services (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.

On October 15, 2015, we announced the launch of the OMIDRIAssure Reimbursement Services Program whereby we expect to expand broadly patient access to Omidria by providing reimbursement support services, 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.

Distribution Fees and Product Returns. 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 against product sales for these charges at the time of sale to the wholesaler.

For all wholesalers, 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 and historical industry return rates.

License Agreement Revenues

We have entered into an exclusive licensing agreement for OMS103 with Fagron Compounding Services, LLC, d/b/a Fagron Sterile Services and JCB Laboratories, LLC (collectively, Fagron). Under the terms of the license agreement, Fagron is obligated to manufacture and commercialize OMS103 in the U.S. and to pay Omeros royalties generated from sales of licensed products related to OMS103 plus milestone payments on reaching certain aggregate sales thresholds. Royalty revenues, of which there were none as of September 30, 2015, will be recognized as revenue if and when Fagron sells the product. Aggregate revenue milestones will be recognized as revenue if and when the related sales threshold is achieved.

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, fair market value of investments, 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.

Liquidity and Capital Resources

As of September 30, 2015, we had $35.0 million in cash, cash equivalents and short-term investments. We believe that our existing cash, cash equivalents and short-term investments and revenues, together with capital that we may have the opportunity to raise through public or private equity securities sales, 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 will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes for at least the next 12 months. If we are unable to raise additional capital as and when needed, 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 capital requirements through reduction of our expenses by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities during the next 12 months.

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, 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 by reserving for excess and obsolete inventories based on forecasted demand. As of September 30, 2015, all inventory is finished goods for Omidria.

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.

Recent Accounting Pronouncements

In July 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 April 2015, the FASB issued 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. This standard is effective for interim and annual periods beginning after December 15, 2015 and early adoption is permitted. We are currently evaluating in which period we will transition and the presentation of the debt liability on our balance sheet following such transition, as well as how related disclosures will be impacted. The disclosures required are those applicable for a change in accounting principle.

In August 2014, the 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, the 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 2—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 three and nine months ended September 30, 2015 and 2014 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:

	September 30,	
	2015	2014
Outstanding options to purchase common stock	8,356,816	6,779,998
Warrants and pre-funded warrants to purchase common stock	1,149,249	604,327
Total	9,506,065	7,384,325

Note 3—Cash, Cash Equivalents and Investments

As of September 30, 2015 and December 31, 2014, all investments are classified as short-term and available-for-sale on the accompanying Condensed Consolidated Balance Sheets. We did not own any securities with unrealized loss positions as of September 30, 2015 or December 31, 2014. Investment income consists primarily of interest earned.

Note 4—Fair-Value Measurements

On a recurring basis, we measure certain financial assets at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The accounting standard 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:

	September 30, 2015			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash	$ 679	$ —	$ —	$ 679
Money-market funds classified as short-term investments	34,398	—	—	34,398
Total	$ 35,077	$ —	$ —	$ 35,077

	December 31, 2014			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash	$ 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 $601,000 and $354,000 is excluded from our fair-value hierarchy disclosure as of September 30, 2015 and December 31, 2014, respectively. There were no unrealized gains and losses associated with our short-term investments as of September 30, 2015 or December 31, 2014. The carrying amounts reported in the accompanying Condensed Consolidated Balance 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 5—Accrued Liabilities

Accrued liabilities consisted of the following:

	September 30, 2015	December 31, 2014
	(In thousands)	
Consulting and professional fees	$ 2,533	$ 1,952
Employee compensation	2,228	2,421
Contract research	1,700	1,280
Clinical trials	1,268	828
Other accruals	392	589
Total accrued liabilities	$ 8,121	$ 7,070

Note 6—Notes Payable

In March 2014, we entered into a Loan and Security Agreement (the Oxford/MidCap Loan Agreement) with Oxford Finance LLC (Oxford) and MidCap Financial SBIC, LP (MidCap) pursuant to which we borrowed $32.0 million, of which $27.3 million is outstanding as of September 30, 2015. We used approximately $19.1 million of the loan proceeds to repay all of the amounts owed by us under our then outstanding loan 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. Beginning April 1, 2015, monthly principal and interest payments of $1.0 million are due through the maturity date of March 1, 2018. In addition, the Oxford/MidCap Loan Agreement requires payment of a $2.2 million loan maturity fee upon full repayment of the loan. 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, which would be waived if we refinance the indebtedness with Oxford and MidCap and pay the loan maturity fee. As security under the Oxford/MidCap Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property.

The Oxford/MidCap Loan Agreement contains covenants that limit or restrict our ability to enter into certain transactions, and it also includes provisions related to events of default, the occurrence of a material adverse effect (MAE) and changes of

control. The occurrence of an event of default could result in the acceleration of the Oxford/MidCap Loan Agreement and, under certain circumstances, could increase our interest rate by 5.0% per annum during the period of default.

As of September 30, 2015, the remaining unamortized discount and debt issuance costs associated with the debt were $1.1 million and $167,000, respectively, and are being amortized to interest expense using the effective interest method through the loan maturity date.

Note 7—Commitments and Contingencies

Real Estate Obligations

We lease office and laboratory spaces in The Omeros Building. 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 September 30, 2015, the remaining aggregate non-cancelable rent payable under the initial term of the lease was approximately $55.5 million. The deferred rent balance relates to rent deferrals since the inception of our lease and is being amortized to research and development as well as selling, general and administrative expense on a straight-line basis through the initial term of the lease.

Contracts

We have an agreement with Ventiv Commercial Services, LLC (inVentiv) for field sales representatives and related sales operation services for Omidria in the U.S. We can terminate the agreement upon 30 days written notice if Omidria is withdrawn from the market for any reason or a regulatory agency acts to prevent or materially restrict the sale of Omidria, or upon 90 days written notice at any time subsequent to January 2016. As of September 30, 2015, our commitment under the agreement is approximately $630,000 per month through January 2016 and $315,000 per month thereafter through June 2016.

We have a non-exclusive agreement with Patheon Manufacturing Services LLC (Patheon) for commercial supply of Omidria through December 31, 2015. Pursuant to the terms of the contract, we are required to provide a monthly, non-binding production forecast covering the term of the contract. Upon submission of the monthly forecast, a portion of the forecast becomes a firm purchase commitment. In the event we do not purchase the quantities included in the firm purchase commitment, we would owe a cancellation fee. As of September 30, 2015, we had a firm purchase commitment requiring payment of approximately $842,000.

We have a non-exclusive agreement with Hospira Worldwide, Inc. (Hospira) for commercial supply of Omidria. We have no firm purchase commitments under this agreement until, in connection with the commencement of commercial manufacturing of Omidria by Hospira, we provide monthly rolling forecasts that will be used to calculate our firm purchase commitment. We have not commenced commercial manufacturing of Omidria by Hospira as of September 30, 2015 and, therefore, we do not currently have any firm purchase commitments outstanding under this agreement.

Development Milestones and Product Royalties

We have retained control of worldwide commercial rights to Omidria, to all of our product candidates and to our programs other than OMS103. We potentially owe certain development milestones and sales-based royalties on commercial sales of certain product candidates within our pipeline. These are low single-digit royalties based on net sales or net income as more fully described in our 2014 Annual Report on Form 10-K filed with the SEC on March 16, 2015.

Litigation

On July 27, 2015, we received notice from Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC, (collectively, Par) 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 notice of Paragraph IV certification, 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. 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 of valid claims. 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 the end of January 2018. We have reviewed the assertions in Par's notice of Paragraph IV certification and believe they do not have merit, and we intend to prosecute vigorously our patent infringement claims against Par.

Note 8—Shareholders' Equity

Common Stock

In February 2015, we sold 3.4 million shares of our common stock at a public offering price of $20.03 per share 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 our common stock, less the $0.01 per share exercise price of each pre-funded warrant. If not exercised, the pre-funded warrants will expire on February 3, 2022. After deducting underwriter discounts and offering expenses of $4.9 million, we received net proceeds from the offering 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 offering expenses and underwriter discounts of $2.5 million, we received net proceeds from the transaction of $37.8 million.

Warrants

The following table summarizes our total outstanding warrants as of September 30, 2015, which have a weighted average exercise price of $10.45:

Outstanding At September 30, 2015	Expiration Date	Exercise Price ($)
133,333	October 21, 2015	20.00
133,333	October 21, 2015	30.00
133,333	October 21, 2015	40.00
749,250	February 3, 2022	0.01
1,149,249		

In October 2010, in connection with the Vulcan agreement, we issued three warrants to purchase our common stock, each exercisable for 133,333 shares, with exercise prices of $20, $30 and $40 per share, respectively. The warrants were not exercised and expired on October 21, 2015.

In each of March 2014 and September 2014, we extended the expiration dates of warrants to purchase approximately 197,000 shares of our common stock at an exercise price of $12.25 per share by six months that, collectively, extended the final expiration date of these warrants to March 29, 2015. We evaluated the fair value of the warrants before and after each modification and for the three and nine months ended September 30, 2014, we recorded the $411,000 and $863,000, respectively, change in fair value as other expense in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss. Between January 1, 2015 and the March 29, 2015 expiration date, we received proceeds of $1.4 million upon the exercise of warrants to purchase approximately 136,000 shares of our common stock.

Note 9—Stock-Based Compensation

On January 1, 2015, in accordance with provisions of our 2008 Equity Incentive Plan, the authorized shares available for grant were increased by 1,709,273 shares. As of September 30, 2015, a total of 10,106,684 shares were reserved for issuance under our stock plans, of which 1,749,868 were available for future grants.

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 and director stock option grants during the periods ended:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Estimated weighted-average fair value	$ 8.09	$ 10.18	$ 12.08	$ 8.39
Weighted-average assumptions				
Expected volatility	74%	70%	70%	82%
Expected term, in years	6.0	6.1	5.9	5.9
Risk-free interest rate	1.68%	1.95%	1.63%	1.90%
Expected dividend yield	—%	—%	—%	—%

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Research and development	$ 1,231	$ 879	$ 3,784	$ 2,791
Selling, general and administrative	1,145	786	3,489	2,292
Total	$ 2,376	$ 1,665	$ 7,273	$ 5,083

Stock option activity for all stock plans and related information 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	265,725	19.26		
Exercised	(205,894)	5.51		
Forfeited	(67,484)	13.28		
Balance at September 30, 2015	8,356,816	$ 7.90	6.38	$ 29,156
Vested and expected to vest at September 30, 2015	8,116,603	$ 7.78	6.31	$ 29,035
Exercisable at September 30, 2015	5,989,625	$ 6.38	5.48	$ 27,928

At September 30, 2015, there were 2,367,191 unvested options outstanding that will vest over a weighted-average period of 2.2 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these options is $14.5 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the unaudited consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q.

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 is currently being sold in the U.S. 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 also have five clinical-stage development programs in our pipeline, which includes a diverse group of preclinical programs as well as 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.

Products, Product Candidates, Development Programs and Platforms

Products

Omidria. 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. We commenced a controlled launch of Omidria to a small number of ambulatory surgery centers, or ASCs, in the U.S. in February 2015. In April 2015 we initiated the broad U.S. launch of Omidria and began selling Omidria primarily through wholesalers which, in turn, sell to 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 through December 31, 2017. Pass-through status allows for separate 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. In addition, on October 15, 2015, we announced the launch of the OMIDRIAssure Reimbursement Services Program whereby we expect to expand broadly patient access to Omidria by providing reimbursement support services, free product based on the financial need of government-insured or uninsured patients in our "Equal Access" Patient Assistance Program, and financial assistance for patients whose commercial insurance is inadequate to cover fully the cost of Omidria in our "We Pay the Difference" Commercial Reimbursement Program. We have also 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 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), prevent miosis (pupil constriction), and 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. In the EU and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria. Timing of any such partnerships depends on numerous factors, including domestic sales of Omidria.

In July 2015, we received notice from Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC, together Par, that Par has filed an Abbreviated New Drug Application, or 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, or Orange Book, for Omidria, or the Orange Book Patents. Following receipt of the notice of Paragraph IV certification, in September 2015 we filed suit under the Hatch-Waxman Act for patent infringement 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. 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 of valid claims. The filing of suit against Par triggered a 30-month stay of FDA's approval of Par's ANDA, which is expected to remain in effect until the end of January 2018. We have reviewed the assertions in Par's

notice of Paragraph IV certification and believe they do not have merit, and we intend to prosecute vigorously our patent infringement claims against Par.

OMS103. 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. 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 yet commenced sales under the OMS103 Agreement. Based on communications with Fagron, we do not expect sales of OMS103 to commence in 2015. We and Fagron are in discussions concerning timing of the initiation of sales under the OMS103 Agreement.

Product Candidates

We have a pipeline of development programs targeting immune-related disorders, pain, inflammation, coagulopathies and disorders of the central nervous system. We have the following five clinical-stage programs in our pipeline:

- *MASP - OMS721*. OMS721, our lead MASP-2 antibody, is in a Phase 2 clinical program in patients with complement-mediated thrombotic microangiopathies, or TMAs. OMS721 has received Orphan Drug designation for the prevention (inhibition) of complement-mediated TMAs and Fast Track designation for the treatment of patients with atypical hemolytic uremic syndrome, or aHUS, a form of TMA. 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. Chronic preclinical toxicity studies have been completed and demonstrated no safety concerns, allowing chronic dosing in clinical trials. Additional patients were enrolled in the high-dose cohort, and an additional patient in the high-dose cohort of the dose-ranging stage has completed dosing. This patient has a history of lymphoma for which he underwent hematopoietic stem cell transplant, or HSCT. His post-transplant course has been complicated by a number of life-threatening disorders, including platelet transfusion-requiring TMA. Despite transfusions, the patient's TMA persisted and he was enrolled in our OMS721 Phase 2 trial. Following the four-week dosing period, platelet count quadrupled, resulting in a count of more than 100,000; haptoglobin level more than doubled and was normal; plasma lactate dehydrogenase level, a measure of damage within blood vessels, decreased by 35 percent but still above normal; and schistocyte (i.e., fragmented red blood cell) count remained at only one. Throughout dosing with OMS721 and since completing OMS721 treatment, the patient has not required platelet transfusions or plasmapheresis. The fixed-dose stage of the Phase 2 clinical trial is expected to continue in 2016. We are preparing to discuss Phase 3 trial design with FDA later this year or in the early part of 2016. In addition, investigator-requested compassionate use for OMS721 continues to be available to European patients with aHUS for whom it has been and will be requested. Based on the positive efficacy and safety data in TMAs, we are currently expanding clinical trials to evaluate OMS721 in IgA nephropathy and other complement-related renal disorders.

- *PDE10 - OMS824 for Huntington's disease and Schizophrenia*. OMS824, our lead phosphodiesterase 10, or PDE10, inhibitor, 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 evaluating OMS824 in Huntington's were previously suspended at the request of the FDA. Recently, based on review of our submission of requested data, the FDA notified us that we are permitted to resume clinical trials in our Huntington's program, with dosing limitations. The dosing limitations are subject to removal pending submission and FDA review of additional information. We are moving forward with the Huntington's program and will generate additional data for further discussion with 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. 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.

- *PPARγ - OMS405*. In our peroxisome proliferator-activated receptor gamma, or PPARγ, program, Phase 2 clinical trials have been conducted by our collaborators to evaluate a PPARγ agonist, alone or in combination with other agents, for treatment of addiction to opioids and to nicotine. Data are expected to be available later this year or in the early part of 2016.

- *OMS201-Urology*. OMS201, our PharmacoSurgery product candidate for use during urological procedures, including uroendoscopic procedures, completed a Phase 1/Phase 2 clinical trial in 2010 and is not currently in active clinical trials.

Development Programs and Platforms

Our preclinical programs include:

- *PDE7*. In our PDE7 program, we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders.
- *Plasmin*. 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).
- *MASP-3*. In our MASP-3 program, OMS906, we are developing MASP-3 inhibitors for the treatment of disorders related to the alternative pathway of the complement system and currently are optimizing potent and functionally active antibodies in preparation for scale-up of one or more clinical candidates.
- *GPCR*. In our orphan GPCR program, we are conducting *in vivo* preclinical efficacy studies and optimizing compounds for a number of targets including GPR17 linked to myelin formation, GPR101 linked to obesity, GPR151 linked to neuropathic pain, GPR161 linked to cancer and GPR174 and GPR183 linked to immune disorders.

We have two additional platforms: one used to generate antibodies and the other capable of unlocking new GPCR drug targets.

Financial Summary

We recognized net losses of $19.9 million and $18.3 million for the three months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, our accumulated deficit was $383.3 million, total shareholders' deficit was $9.0 million and we had $35.0 million in cash, cash equivalents and short-term investments.

Results of Operations

Revenue

Our revenue consists of product sales of Omidria and revenue recognized in connection with third party grant funding.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Product sales, net	$ 3,244	$ —	$ 6,607	$ —
Small Business Innovative Research Grants (SBIR)	15	214	227	359
Total revenue	$ 3,259	$ 214	$ 6,834	$ 359

The increase in revenue during the three and nine months ended September 30, 2015 compared to the same periods in 2014 was due to the initiation of U.S. sales of Omidria in 2015.

Product Sales, Net

We initially began selling Omidria in the U.S. on a limited basis in February 2015 followed by the broad based launch in April 2015. During the quarter ended September 30, 2015, Omidria reported revenue increased by $120,000, or four percent, from the prior quarter. Omidria units shipped by our wholesalers during the third quarter, however, increased by 71% from the prior quarter according to data we receive from our wholesalers. Wholesaler buying patterns in the third quarter are responsible for the significant difference between reported revenues and wholesaler units shipped to ASCs and hospitals.

We record Omidria product sales net of estimated chargebacks, rebates, distribution fees, and product returns. These deductions to determine product sales, net are generally referred to as gross-to-net deductions. A summary of our 2015 gross-to-net provision, net of payments, is 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	103	285	388
Payments/credits for current period sales	(39)	(85)	(124)
Balance as of September 30, 2015	$ 64	$ 200	$ 264

Chargebacks and Rebates. We have entered into agreements with various entities that include certain mandatory government discounts or rebates on eligible purchases of Omidria. We identify the entities that purchase Omidria and that are eligible for discounted pricing or rebates and, utilizing our historical chargeback information and projected payer mix, we estimate chargebacks and rebates for these entities at the time of sale to the wholesaler.

On October 12, 2015, we entered into an agreement with Apexus, an authorized 340B prime vendor entitling its customers to purchase Omidria from our wholesalers at a greater discount (i.e., sub-340B/sub-WAC) than those offered under our PHSA Pharmaceutical Pricing Agreement. In addition, on October 15, 2015, we announced the launch of the OMIDRIAssure Reimbursement Services Program whereby we expect to expand broadly patient access to Omidria by providing reimbursement support services, 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 costs of Omidria. We do not expect OMIDRIAssure to have a material adverse impact on Omidria's gross-to-net deductions.

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. Average selling price for Omidria used to compute Medicare reimbursement has remained unchanged in the fourth quarter of 2015.

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 against product sales for these charges at the time of sale to the wholesaler. We expect distribution fees to fluctuate in correlation with gross product sales.

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 experience to date and historical industry return rates.

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, contract research organizations, or 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Direct external expenses:				
Clinical research and development:				
OMS721	$ 5,576	$ 1,778	$ 9,971	$ 6,421
Omidria	647	1,479	2,374	3,933
OMS824	266	2,940	1,317	9,700
Other clinical programs	11	41	29	56
Total clinical research and development	6,500	6,238	13,691	20,110
Preclinical research and development	281	413	1,110	1,403
Total direct external expenses	6,781	6,651	14,801	21,513
Internal, overhead and other expenses	5,252	4,242	14,897	11,892
Stock-based compensation expense	1,231	879	3,784	2,791
Total research and development expenses	$ 13,264	$ 11,772	$ 33,482	$ 36,196

The increase in total clinical research and development expenses during the three months ended September 30, 2015 compared to the same period in 2014 was due primarily to increased costs for our OMS721 program in connection with manufacturing and clinical research and development. This increase was offset by lower clinical research and development costs related to our OMS824 program due to its 2014 clinical suspension and lower Omidria clinical trial costs.

The decrease in total clinical research and development expenses during the nine months ended September 30, 2015 compared to the same period in 2014 was due primarily to reduced costs for our OMS824 program. During the first quarter of 2014, we manufactured material for the OMS824 Phase 1 and Phase 2 clinical trials. We also incurred Phase 1 and Phase 2 clinical trial costs in 2014 until the suspension of clinical enrollment. Additional decreases included lower clinical trial costs for Omidria. These decreases in clinical research and development costs were partially offset by increased manufacturing costs and clinical trial costs for our OMS721 program.

In addition, internal, overhead and other expenses increased during the three and nine months ended September 30, 2015 compared to the same periods in 2014 due to increased headcount and stock-based compensation expense related to annual company-wide option grants approved in October 2014.

We anticipate that total research and development costs will increase during the remainder of this year due to planned clinical manufacturing and clinical study activities.

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 given 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 become available and as expectations change. While we are focused currently on advancing our product development programs, our future research and development expenses will depend, in part, on the preclinical or clinical success of each product candidate as well as ongoing assessments of each program's commercial potential. Our future research and development expenses might also depend on the commercial success of Omidria as well as royalty payments from Fagron with respect to OMS103 sales. In addition, we 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 delay our generation of product revenue and increase our research and development expenses and, in turn, 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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Selling, general and administrative expenses, excluding stock-based compensation expense	$ 7,903	$ 4,788	$ 22,437	$ 11,904
Stock-based compensation expense	1,145	786	3,489	2,292
Total selling, general and administrative expenses	$ 9,048	$ 5,574	$ 25,926	$ 14,196

The increase in selling, general and administrative expenses during the three and nine months ended September 30, 2015 compared to the same periods in 2014 was primarily due to sales and marketing costs incurred in connection with the sales force, marketing materials and events, speakers bureaus and legal costs to support the market launch of Omidria. The increase in stock-based compensation expense during the three and nine months ended September 30, 2015 compared to the same periods in the prior year were primarily due to annual company-wide option grants approved in October 2014. We anticipate selling, general and administrative costs will increase during the remainder of this year primarily due to increased costs in connection with the support of the Omidria market launch.

We intend to hire inVentiv-supplied field sales representatives as Omeros employees on January 1, 2016 and to continue to receive back office sales management and systems support from inVentiv on a month-to-month basis. We anticipate that the conversion will not have a material effect on the overall costs currently incurred for the hired representatives and related systems support.

Interest Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Interest expense	$ 871	$ 944	$ 2,765	$ 2,555

The decrease in interest expense during the three months ended September 30, 2015 compared to the same quarter in the prior year is primarily due to principal payments being made on the Oxford/MidCap Loan Agreement.

The increase in interest expense during the nine months ended September 30, 2015 compared to the same period in 2014 was due to $12.7 million of incremental borrowings requiring interest only payments until April 1, 2015.

Investment Income and Other Income (Expense), Net

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)		(In thousands)	
Investment income and other income (expense), net	$ 251	$ (251)	$ 693	$ (372)

Investment income and other income (expense), net includes interest and sublease rental income, and for three and nine month periods ended September 30, 2014, also includes non-cash charges of $411,000 and $863,000, respectively, associated with extending the exercise period of warrants to purchase 197,000 shares of our common stock by six months in each of March 2014 and September 2014, respectively.

Financial Condition - Liquidity and Capital Resources

As of September 30, 2015, we had $35.0 million in cash, cash equivalents and short-term investments that are held principally in interest-bearing instruments, including money-market accounts. Cash in excess of our immediate requirements is invested in accordance with established guidelines intended to preserve principal and maintain liquidity.

We believe that our existing cash, cash equivalents and short-term investments and revenues, together with capital that we may have the opportunity to raise through public or private equity securities sales, 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, will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes for at least the next 12 months. If we are unable to raise additional capital as and when needed, 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 capital requirements through reduction of our expenses by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities during the next 12 months.

	Nine Months Ended September 30,	
	2015	2014
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	$ (48,609)	$ (42,353)
Investing activities	(28,053)	(8,325)
Financing activities	76,909	50,044

Operating Activities. Net cash used in operating activities was $48.6 million for the nine months ended September 30, 2015. The cash used in operating activities was affected by a net loss of $55.3 million, partially offset by stock-based compensation expense of $7.3 million and a $2.1 million increase in receivables. The increase in receivables relates to increased Omidria sales in 2015 which generally have up to 90 day terms.

Net cash used in operating activities was $42.4 million for the nine months ended September 30, 2014. The cash used in operating activities was affected by a net loss of $53.0 million, partially offset by stock-based compensation expense of $5.1 million and a $3.9 million increase in accounts payable. The increase in accounts payable relates to the timing of payments.

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 these fluctuations in cash flows to be important to the understanding of our liquidity and capital resources.

Net cash used in investing activities in the nine months ended September 30, 2015 was $28.1 million, an increase of $19.7 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. These purchases were partially offset by the sale of $51.6 million of short-term investments to provide cash for operating activities.

Financing Activities. Net cash provided by financing activities in the nine months ended September 30, 2015 was $76.9 million, an increase of $26.9 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. During the 2014 period, cash was primarily provided by the $37.8 million of net proceeds from the sale of 3.5 million shares of common stock in our public offering and the net additional borrowings of $12.7 million under the Oxford/MidCap Loan Agreement.

Contractual Obligations and Commitments

The following table presents a summary of our contractual obligations and commitments as of September 30, 2015:

	Payments Due Within				
	1 Year	2-3 Years	4-5 Years	More than 5 Years	Total
	(In thousands)				
Operating leases	$ 4,083	$ 8,410	$ 8,750	$ 34,389	$ 55,632
Capital leases (principal and interest)	54	103	13	—	170
Notes payable (principal and interest)	12,256	18,384	—	—	30,640
Goods & services	5,061	—	—	—	5,061
Total	$ 21,454	$ 26,897	$ 8,763	$ 34,389	$ 91,503

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 September 30, 2015, the remaining aggregate non-cancelable rent payable under the initial term of the lease was approximately $55.5 million.

Notes Payable

We have borrowed $32.0 million under the Oxford/MidCap Loan Agreement that required interest-only payments at an annual rate of 9.25% through March 2015. Beginning April 1, 2015, monthly principal and interest payments of $1.0 million became due through the maturity date of March 1, 2018. In addition, the Oxford/MidCap Loan Agreement requires a $2.2 million loan maturity fee and, if applicable, a prepayment fee, upon full repayment of the loan.

Goods & Services

In June 2014, we entered into an agreement with Ventiv Commercial Services, LLC, or inVentiv, for field sales representatives and related sales operation services for the U.S. commercial launch of Omidria. In October 2014, we amended the agreement to add additional sales representatives in the U.S. As of September 30, 2015, we had a monthly commitment of approximately $630,000 under the agreement and related amendment through January 2016 and $315,000 per month thereafter through June 2016. We can terminate the agreement upon 30 days written notice if Omidria is withdrawn from the market for any reason or a regulatory agency acts to prevent or materially restrict the sale of Omidria, or upon 90 days written notice at any time subsequent to January 2016 for the original group of sales representatives and subsequent to June 2016 for the remaining sales representatives. The $4.2 million of estimated costs for this agreement through June 2016 are included in the table above. We intend to hire inVentiv-supplied field sales representatives as Omeros employees on January 1, 2016 and continue to receive back-office sales management and systems support from inVentiv on a month-to-month basis.

We have a non-exclusive agreement with Patheon Manufacturing Services LLC, or Patheon, for commercial supply of Omidria through December 31, 2015. We are required to provide a monthly, non-binding production forecast covering the term of the contract. Upon submission of the monthly forecast, a portion of the forecast becomes a firm purchase commitment. In the event we do not purchase the quantities included in the firm purchase commitment, we would owe a cancellation fee. The firm purchase commitment of approximately $842,000 as of September 30, 2015 is included in the table above.

We also have a non-exclusive agreement with Hospira Worldwide, Inc., or Hospira, for commercial supply of Omidria. We are working with Hospira to validate the manufacturing process for Omidria at one of its facilities, and this activity is not expected to be completed earlier than the second half of 2016. Our agreement with Patheon for the commercial supply of Omidria at a specific Patheon facility expires at the end of 2015. As a result, we do not expect that Omidria manufacturing will be in production for several months in 2016, at the earliest. This interruption in manufacturing was anticipated and is being addressed through increased production of Omidria prior to the break in manufacturing. Together with at least two years of product shelf life, we believe that we will have sufficient supply to meet product needs until restoration of product production in 2016.

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 8 to our Consolidated Financial Statements in our 2014 Annual Report on Form 10-K filed with the SEC on March 16, 2015 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 condensed 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.

Revenue Recognition

Our revenues are comprised of product sales of Omidria and amounts earned for services under grants from the National Institutes of Health, or NIH. 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. We record Omidria product revenue upon delivery to our wholesalers or upon shipment to the ASC or hospital for direct sales. 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, distribution fees and estimated product returns utilizing a variety of information including our historical and projected payer mix, our historical experience as well as industry averages, sale-through and inventory on-hand information received directly from wholesalers, changes in the overall marketplace, and the remaining shelf life of product that we have previously sold. Accruals are established for these deductions when revenue is recognized and actual amounts incurred are offset against the applicable accruals. 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.

Product Sales, Net

Chargebacks and Rebates. We have entered into agreements with various entities that include certain contractual discounts or rebates on eligible purchases of Omidria. Under certain agreements, our wholesalers forward a chargeback to us for the difference between wholesale acquisition cost, or WAC, and the applicable discounted price. We identify the entities that purchase Omidria and which are eligible for discounted pricing or rebates and, utilizing our historical chargeback information and projected payer mix, we estimate chargebacks and rebates for these entities.

We have entered into a Medicaid Drug Rebate Agreement with CMS that provides a rebate to participating states based on covered purchases of Omidria. We estimate Medicaid rebates based on our payer mix and historical information for Omidria.

On October 12, 2015, we entered into an agreement with Apexus, an authorized 340B prime vendor entitling Apexus' customers to purchase Omidria from our wholesalers at a greater discount (i.e., sub-340B/sub-WAC) than those offered under our PHSA Pharmaceutical Pricing Agreement. In addition, on October 15, 2015, we announced the launch of the OMIDRIAssure Reimbursement Services Program whereby we expect to expand broadly patient access to Omidria by providing reimbursement support services, 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 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. Average selling price for Omidria has remained unchanged in the fourth quarter of 2015.

Distribution Fees and Product Return Allowances. We pay our wholesalers a distribution fee for services that they perform for us based on the dollar 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, 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 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 and historical industry return rates.

For a more detailed listing of our other critical accounting policies and significant judgments and estimates, refer to our 2014 Annual Report on Form 10-K filed with the SEC on March 16, 2015.

Off-Balance Sheet Arrangements

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

ITEM 3. 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 September 30, 2015, we had cash, cash equivalents and short-term investments of $35.0 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These 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 4. CONTROLS AND PROCEDURES

Evaluation of 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 September 30, 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 September 30, 2015, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On September 2, 2015, we filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey and on September 3, 2015, filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par. The lawsuits were filed under the Hatch-Waxman Act for Par's infringement of three Omeros patents, U.S. Patent Nos. 8,173,707, 8,586,633 and 9,066,856, which relate to Omidria and which are listed in the Orange Book published by the FDA. The lawsuits were filed following our receipt of a Paragraph IV certification notice that we received from Par, dated July 23, 2015, regarding Par's filing with the FDA an ANDA seeking approval to market a generic version of Omidria prior to the expiration of the three Orange Book-listed patents for Omidria. 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. Under the Hatch-Waxman Act, we were permitted to file suit within 45 days from receipt of Par's notice and thereby trigger a 30-month stay of the FDA's approval of Par's ANDA. The stay is expected to remain in effect until the end of January 2018. We have reviewed the assertions in Par's notice of Paragraph IV certification and believe they do not have merit, and intend to prosecute vigorously our patent infringement claims against Par.

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 Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2014.

Risks Related to Our Products, Programs and Operations

If we are unable to successfully commercialize Omidria, or any of our product candidates, if approved, our inability to generate significant revenue from the sales of Omidria or any other approved products would adversely impact our ability to achieve profitability.

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 months ended September 30, 2015, we recorded net sales of Omidria of $3.2 million. We have not generated revenue from sales of Omidria to date that are sufficient to fund our operations and do not expect to generate sufficient revenue from Omidria to fund our operations in the near term. To achieve sustained profitability, we will need to generate substantially more product revenue from Omidria or our product candidates that may receive approval. Our ability to generate significant revenue from Omidria product sales depends on our ability to achieve increased market acceptance of, and to otherwise effectively commercialize, Omidria. We may not be able to commercialize successfully Omidria or any product candidate, if approved, for a number of reasons, including:

- a lack of acceptance by physicians, patients, third-party 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;
- our reliance on a sole manufacturer or limited number of manufacturers and our reliance on a limited number of suppliers of the product's active pharmaceutical ingredients, excipients and packaging materials;
- 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 competing products;
- an unknown safety risk of Omidria or any product candidate;
- the failure to obtain regulatory approval;
- the failure to enter into and maintain acceptable partnering arrangements for marketing and distribution of products, including for Omidria, outside of the U.S.;
- an inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- changed or increased regulatory restrictions in the U.S., EU and other foreign territories; and

- a lack of adequate financial or other resources to commercialize the product successfully.

If we are not able to commercialize successfully Omidria or any other product candidate, if approved, for these or other reasons, our ability to generate revenue from product sales and achieve profitability will be adversely affected and the market price of our common stock could decline significantly.

Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

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 of demand for Omidria;
- the level and timing of commercial sales of Omidria;
- the extent to which coverage and reimbursement for Omidria is available from government and private third-party payers such as Medicare, Medicaid, the VA, insurance companies, group purchasing organizations, health maintenance organizations and other plan administrators;
- the amount of chargebacks, rebates and product returns for Omidria;
- the ability of the OMIDRIAssure Reimbursement Services Program to increase meaningfully patient access to Omidria;
- the continued availability of adequate reimbursement for Omidria once transitional pass-through reimbursement expires;
- the timing, cost and level of investment in our sales and marketing efforts to support Omidria sales;
- the ability and commitment of Fagron to manufacture and commercialize OMS103 successfully and the level of royalties, if any, paid to Omeros by Fagron;
- the timing, cost and level of investment in our research and development activities involving Omidria and our product candidates; and
- the timing and cost of conducting required post-approval studies for Omidria and 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 OMS103 is used, or the size of the market in which any other of our products would be used, if commercialized, may be significantly less than the total number of such procedures performed or total possible market size. Our revenues may also depend on commercial arrangements, development funding and the achievement of development and clinical milestones under collaboration and license agreements that we may enter into from time to time in the future, including without limitation our exclusive license agreement for the U.S. commercialization of OMS103. Upfront and milestone payments, as well as payments based on product sales, under these arrangements may vary significantly from quarter to quarter and any such variance could cause a significant fluctuation in our operating results from one quarter to the next.

These and other factors, including our limited history of product sales, may make it difficult for us to forecast and provide in a timely manner public guidance (including updates to prior guidance) related to our projected financial performance.

If we are unable to market and successfully sell and/or distribute Omidria, or our product candidates if approved, our ability to generate revenue may be limited.

Prior to the U.S. launch of Omidria, Omeros had never marketed, sold or distributed any product. If we are unsuccessful in building or managing a sales and marketing infrastructure internally or through one or more third-party partners for any product or approved product candidates in the U.S. or elsewhere, or if any of those third-party partners fail to perform as necessary, we will have difficulty marketing and selling successfully the product or commercializing the product candidate, which would adversely affect our business and financial condition. We intend to hire inVentiv-supplied field sales representatives as Omeros employees on January 1, 2016 continue to receive back-office sales management and systems support from inVentiv on a month-to-month basis. We have only limited experience in maintaining a commercial sales force on our own, and we may not be able to maintain successfully the Omeros-employed sales representatives in a cost-effective or timely manner, or otherwise realize a positive return on our investment. We will also have to compete with other pharmaceutical and life sciences companies to recruit and retain our dedicated sales team. Because of the numerous risks and uncertainties involved with establishing and maintaining a commercial sales force, we may experience difficulties commercializing Omidria successfully, which would adversely affect our business and financial results.

In the EU, we plan to enter into partnerships for the marketing and distribution of Omidria with one or more third parties. 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. Even if we could obtain approvals from additional relevant government authorities in one or more non-U.S. territories, we would not expect to see sales of Omidria in those territories if we are unable to enter into such agreements on terms acceptable to us, if at all, which could adversely affect our business and financial condition.

We have incurred cumulative operating losses since inception and are unable to predict whether or when we will become profitable. If we are unable to raise additional capital when needed, we may be unable to continue commercialization of Omidria, 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 September 30, 2015, we had an accumulated deficit of approximately $383.3 million. We expect to continue to spend substantial amounts to:

- continue the commercialization of Omidria;
- continue research and development in all of our programs;
- make principal and interest payments under the Oxford/MidCap Loan Agreement;
- initiate and conduct clinical trials for other programs and product candidates; and
- commercialize and launch any product candidates for which we 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 or whether or when we will become profitable. To date we have not generated revenue from sales of Omidria that is sufficient to fund our operations. 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 be unable to complete these tasks successfully, or at all, which could prevent us from generating sales revenue or limit the amount of sales revenue generated. Further, 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. If we are unable to raise sufficient capital if and when required, our business and prospects could be harmed and our stock price could decline significantly.

If Omidria or any other product that we may develop and commercialize does not receive adequate reimbursement from governments or other third-party payers, or if we do not establish and maintain market-acceptable pricing for Omidria or those commercialized products, they may not be purchased or used and, as a result, our prospects for revenue and profitability could suffer.

Our future revenues and profitability will depend heavily on the pricing and availability of adequate reimbursement for the use of products that we or our third-party business partners commercialize, including Omidria and, once commercialized, OMS103, from governmental 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. Reimbursement by a third-party payer may depend on a number of factors, including the third-party 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 third-party payers and also depends on complex regulations that may change with annual or more frequent rulemaking and other legislative activities.

Obtaining reimbursement approval for any product from each government or third-party payer can be a time-consuming and costly process that will 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. Even if one payer adopts a favorable reimbursement methodology for a product or product candidate, if commercialized, there is no guarantee that other third-party payers will adopt the same methodology. For example, other third-party payers often follow, but are not required to follow, the reimbursement methodology adopted by CMS. As a result, 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, third-party payers that reimburse for healthcare services and products, such as government and private payers, are requiring that companies provide them with predetermined discounts from list prices and challenging the prices charged for medical products. 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. In addition, pass-through reimbursement status is granted for a limited duration and we expect that pass-through reimbursement status for Omidria will last until December 31, 2017. After pass-through reimbursement status expires, we may not be able to maintain or obtain separate or 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 that we are able to obtain and maintain for any product that we develop, 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 third-party payers, there could be a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our business is subject to extensive government regulation, including the regulations associated with approval for marketing of our product candidates.

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, labeling, advertising, promotion, distribution, and import and export. Failure to comply with applicable requirements could result in, for example, 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. 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.

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. As we develop our product candidates, we periodically discuss with the FDA clinical, regulatory and manufacturing matters, and our views may, at times, differ from those of the FDA. If we are unable to resolve questions raised by the FDA, we may be required to provide additional information, which may necessitate additional preclinical studies or clinical trials. If we are required to conduct additional nonclinical or clinical 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.

Even if regulatory approval of a product candidate is obtained there is no guarantee that the product will be commercially successful or address a clinical need. 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, for example, manufacturing difficulties. As a result of any of these or other problems, a product's regulatory approval could be withdrawn. Any of these outcomes could harm our business and operating results.

Commercialization of Omidria and our product candidates, if approved, is subject to extensive regulation and oversight under a number of different healthcare compliance laws. Compliance with these regulations requires the expenditure of substantial resources and attention, and the failure to comply with these regulations could result in criminal penalties, substantial fines or other civil penalties.

In the U.S., the 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, including the U.S. Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations; the federal Anti-Kickback Law; the federal False Claims Act; and the so-called Sunshine Act and related provisions of the Affordable Care Act. In addition to these federal law requirements, there are related state law requirements, including some laws that restrict our interactions with physicians and other providers. Also, if we receive protected patient health information, we may be subject to federal or state privacy laws. We are subject to a variety of governmental pricing, price reporting, and rebate requirements. These requirements generally require us to pay rebates or provide discounts to government payers in connection with our products. The terms, scope and complexity of these government pricing requirements change frequently. Similar requirements apply to our operations outside the U.S. In addition, many countries have their own laws similar to the healthcare compliance laws that exist in the U.S.

In order to comply with these U.S. and other laws, we must establish and maintain an effective healthcare compliance program. In addition, some states mandate that we have an established compliance program. 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. In addition, if government enforcement authorities initiate an investigation into potential violations of these laws, we would be required 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.

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 the EU and many other 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. The time required to obtain regulatory approval outside the U.S. may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these "Risk Factors" and we may not obtain foreign regulatory approvals on a timely basis, or at all. 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 failure to obtain regulatory approval in one or more foreign jurisdictions, or any delays in the regulatory process, could harm our business. In addition, while Omidria has been approved for marketing in all EU member states plus Iceland, Lichtenstein, and Norway, we have not yet obtained the pricing or reimbursement decisions from those jurisdictions required to market Omidria in each of them.

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 have discontinued our OMS103 clinical development program and are dependent on Fagron to commercialize OMS103 in the U.S. We cannot control whether or not Fagron will fulfill its obligations under the OMS103 Agreement or whether the commercialization of OMS103 will be successful. Fagron has not yet commenced sales under the OMS103 Agreement and has recently expressed concerns regarding its ability to meet some of the diligence milestones in the time frame required, including initial sale of OMS103 in the fourth quarter of 2015.

Assuming Fagron complies with its obligations under the OMS103 Agreement, Fagron may fail to commercialize OMS103 successfully for a number of reasons, including:

- a lack of acceptance by physicians, patients, third-party payers and other members of the medical community, including based on any conclusion that may be reached regarding the efficacy or lack of efficacy of OMS103;
- pricing, reimbursement and coverage policies of government and private payers such as Medicare, Medicaid, the VA, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- the availability, relative price and efficacy of OMS103 as compared to alternative treatment options or competing products;
- an unknown safety risk of OMS103;
- failure to comply with applicable regulatory requirements;
- failure to comply with applicable cGMPs;
- changed or increased regulatory restrictions in the U.S.; and
- a lack of adequate financial or other resources by Fagron to commercialize the product successfully.

We and Fagron are in discussions concerning timing of the initiation of sales under the OMS103 Agreement. If Fagron fails to perform its obligations under the OMS103 Agreement in a timely manner it would adversely affect the likelihood and timing of our receipt of royalty or milestone payments from Fagron under the OMS103 Agreement. Further, if 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 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 Fagron 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.

We rely and intend to continue to rely on third party manufacturers to produce commercial quantities of Omidria and any of our product candidates should they receive regulatory approval. Additionally, we rely and intend to continue to rely on third parties to produce clinical drug supplies 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 manufacture to an approved alternative facility and/or establish additional manufacturing and supply arrangements. Furthermore, in the event that one of our manufacturers fails to comply with FDA and/or other pharmaceutical manufacturing regulatory requirements, we may need to establish additional or replacement manufacturers, potentially with little or no advance notice. 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 existing Omidria manufacturing agreement with Patheon, which is for a specific facility, expires 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 to have a new agreement in place with Patheon for the manufacture of Omidria at an alternate Patheon facility, or with a different manufacturer, to provide a second source of supply for Omidria for several months in 2016. Further, we do not expect that any Omidria manufacturing facility will be in production before the second half of 2016, at the earliest. We have existing product inventories and have committed to manufacturing quantities of Omidria that we believe will be sufficient to meet market demand during the period in which no manufacturing facilities are in production. 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 starting in 2016 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. Any significant delays in the manufacture of clinical or commercial supplies could materially harm our business and prospects.

If the contract manufacturers that we rely on experience difficulties 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 delayed.

Contract manufacturers that we select to manufacture Omidria or our product candidates for commercial supply or for clinical testing may encounter difficulties with the small- and large-scale formulation and manufacturing processes required for such manufacture. These difficulties could result in delays in clinical trials, regulatory submissions, or impact the commercialization of our products and product candidates. Once a product is approved and is marketed, these difficulties could also result in the recall or withdrawal of the product from the market or failure to have adequate supplies to meet market demand. In addition, we and our contract manufacturers must comply with cGMPs that are strictly enforced by the FDA and other regulatory authorities through facilities inspection programs. These cGMPs include quality control, quality assurance and the maintenance of records and documentation. We or our contract manufacturers may be unable to comply with cGMPs or with other FDA, state, local and foreign regulatory requirements. Although we have obligations to review their compliance, we have limited control over our current, and expect to have limited control for any future, contract manufacturers' compliance with these regulations and standards, or with their quality control and quality assurance procedures. Large-scale manufacturing processes that have been developed, or which would be developed in the future, for our product candidates, or establishing or successfully completing technology transfer to additional manufacturers for Omidria, will require validation studies, which the FDA or other regulatory authorities must review and approve. Failure to comply with these requirements by our contract manufacturers could result in the initiation of enforcement actions by the FDA and other regulatory authorities, as well as the imposition of sanctions, including fines and civil penalties, suspension of production, suspension or delay in regulatory approval, product seizure or recall or withdrawal of product approval. If the safety of Omidria or any product candidate supplied by contract manufacturers is compromised due to their failure to adhere to applicable laws or for other reasons, we may not be able to obtain or maintain regulatory approval for or successfully commercialize Omidria or one or more of our product candidates, which would harm our business and prospects significantly.

If one or more of our contract manufacturers were to encounter any of these difficulties or otherwise fail to comply with its contractual obligations, our ability to provide Omidria or product candidates on a commercial scale or to patients in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending on the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

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 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, or 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, we may be unable to develop our product candidates on a timely basis, which will increase our development costs and delay the potential commercialization of our product candidates should they receive regulatory approval.

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 European Medicines Agency, or 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;
- lower than anticipated retention rates of patients in clinical trials;
- the need to repeat or conduct additional clinical trials as a result of problems such as inconclusive or negative results, 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 or an unacceptable study design;
- 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 FDA inspection or review 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; or
- the placement by a regulatory agency of a trial on a clinical hold.

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) or 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 CROs and other third parties.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may also be required to address other factors and these amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards or Ethics Committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to file for regulatory approval or conduct additional clinical trials on the schedule we currently anticipate. Any delays in completing our clinical trials may increase our development costs, would slow down our product development and regulatory submission process, could delay our receipt of product revenue and could make it difficult to raise additional capital. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products and may harm our business.

If we experience delays or difficulties in enrolling patients in our clinical trials, those clinical trials could take longer than expected to complete and our receipt of regulatory approvals could be delayed or prevented.

We may be unable to initiate or continue clinical trials for product candidates or, potentially, for Omidria, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or other regulatory authorities outside the U.S. Patient enrollment for any of our clinical trials also may be affected by other factors, including:

- the severity of the disease under investigation;
- the design of the trial protocol;
- the size of the patient population (e.g., for orphan diseases or for some pediatric indications);
- the availability of competing therapies and clinical trials;
- the regional differences in diagnosis and treatment;
- the eligibility criteria of the study in question;
- the perceived risks and benefits of the product or product candidate under study;

- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately before and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays may result in increased development costs for our products or product candidates, and we may not have or be able to obtain sufficient cash to fund such increased cost when needed, which could result in further delay or termination of the trial.

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 and research institutions, to conduct a portion of our preclinical research. We also rely on third parties, such as medical institutions, clinical investigators and CROs, to assist us in conducting our clinical trials. Nonetheless, we are responsible for confirming that our preclinical research 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 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, we would need to obtain licenses to those active ingredients from those third parties. If we are unable 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 access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, we may not be able to commercialize product candidates from these programs.

Our ability to pursue the development and commercialization of products from our MASP-2 program depends on the continuation of licenses from third parties.

Our MASP-2 program is based in part on intellectual property rights that we licensed on a worldwide exclusive basis from the University of Leicester, the UK Medical Research Council at Oxford University and Helion Biotech ApS, or Helion. The continued maintenance of these agreements requires us to undertake development activities and, if regulatory approval for marketing is obtained, to pay royalties to each of these organizations upon commercialization of a MASP-2 product, such as OMS721. In addition, 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 related to a MASP-2 product, such as the initiation of clinical trials, receipt of marketing approval and reaching specified sales milestones. Our ability to continue development and commercialization of products from our MASP-2 program, including OMS721, depends on our maintaining these exclusive licenses, which cannot be assured.

Our ability to pursue the development and commercialization of product candidates from our MASP-2, MASP-3 and Plasmin programs depends on third-party developers and manufacturers of biologic drug products.

Any product candidate from our MASP-2, MASP-3 or Plasmin programs would be a biologic drug product and we do not have the internal capability to hybridize, clone or manufacture biologics for clinical or commercial use. 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. If we are unable to obtain clinical supplies of drug product for one of these programs, clinical trials or the development of any such product candidate for that program could be substantially delayed until

we can find and qualify another manufacturer, which may increase our development costs, slow down our product development and approval process, delay receipt of product revenue and make it difficult to raise additional capital.

Our 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. For example, our studies of PDE7 inhibitors in different animal models of Parkinson's disease, which may or may not be relevant to the mechanism of action of PDE7 inhibitors in humans, have produced varying results. Further, we cannot be certain that any of our preclinical product development programs will generate product candidates that are suitable for clinical testing. For example, we have not yet generated any products or product candidates from our GPCR program. We may discover that there are fewer druggable targets among the orphan GPCRs than we currently estimate and that, for those orphan GPCRs for which we identify functionally active compounds that we elect to develop independently, we are unable to develop related product candidates that successfully complete preclinical or clinical testing. If we are unable to develop product candidates, potential corporate partners may be unwilling to enter into partnership agreements with us. We also cannot be certain that any product candidates that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

Because we have a number of 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.

Because we have limited resources, we 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. Our resource allocation decisions may cause us to fail to capitalize on viable potential commercial products or profitable market opportunities. Further, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product 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. Case law and policy regarding the breadth of claims allowed in biotechnology patents has continued to evolve 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. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. For example, in the U.S., a determination of patentability by the U.S. Patent and Trademark Office, or USPTO, or validity by a court or other trier of fact requires a determination that the claimed invention has utility and is both novel and non-obvious to those of ordinary skill in the art in view of prior known publications and public information, and that the patent specification supporting the claim adequately describes the claimed invention, discloses the best mode known to the inventors for practicing the invention, and discloses the invention in a manner that enables one of ordinary skill in the art to make and use the invention. These standards may be challenging to meet for patents directed to some of our technologies, including our target-based technologies. 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 impact the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, our licensed patents or patent applications or in third-party patents.

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, nor can we make assurances as to the scope of any claims that may issue from these pending and future patent applications or 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, which could limit patent protection for our products and product candidates and materially harm our business.

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

- we might not have been the first to make the inventions covered by any of our pending U.S. patent applications filed or having priority dates prior to the U.S. having adopted a first-to-file standard on March 16, 2013, or any U.S. patents issued based on such patent applications;
- we might not have been the first to file patent applications on inventions that are the subject of pending foreign patent applications or that are the subject of pending U.S. patent applications filed or having priority dates after March 16, 2013, or any patents issued based on such foreign or U.S. patent applications;
- others may independently develop similar or alternative technologies or products or duplicate any of our technologies or products or product candidates;
- we may not be able to generate sufficient data to support fully patent applications that protect the entire breadth of developments expected to result from our development programs, including the GPCR program;
- it is possible that none of our pending patent applications will result in issued patents or, if issued, that these patents will be sufficient to protect our technology or provide us with a basis for commercially viable products or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws;
- if issued, the patents under which we hold rights may not be valid or enforceable; or
- we may develop additional proprietary technologies or products or product candidates that are not patentable and which are unlikely to be adequately protected through trade secrets if, for example, a competitor were to develop independently duplicative, similar or alternative technologies or products.

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

In July 2015, we received notice from Par that it had 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. We intend to enforce vigorously our intellectual property rights relating to Omidria, including the three patents referenced in Par's notice of Paragraph IV certification and patents that may issue from currently pending patent applications. 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 Office procedures, and, if any of these events occur, we also intend to enforce vigorously relevant patents against them. Any legal action taken to defend our patents, including our suit against Par, will likely be costly, time consuming and distracting to management, could have a material adverse effect on our business, and 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 by the ANDA filer's proposed product. Until the Par matter is finally resolved, the uncertainty of the outcome may cause our stock price to decline. An adverse outcome in such legal action could also result in a generic version of Omidria being launched after the expiration of the mandatory three-year clinical data exclusivity for

Omidria. The introduction of a generic version of Omidria could have a material negative impact on our financial condition and results of operations.

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

If we choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe the patents. 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, 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 partners 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. The pharmaceutical, biotechnology and other life sciences industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our products 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.

Government regulations and initiatives that affect pricing, coverage and reimbursement of drug products could adversely affect our business.

Governments in countries where we operate or anticipate operating have adopted or have shown significant interest in pursuing legislative initiatives to reduce costs of healthcare. We may also be affected by broader legislation addressing federal spending. Any such government-adopted healthcare measures or other legislation could adversely impact the pricing of our products, including Omidria, or the amount of coverage and reimbursement available for our products from governmental agencies or other third-party payers and adversely impact our results of operations.

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 $32.0 million under the Oxford/MidCap Agreement. As collateral for this loan, we pledged substantially all of our assets other than intellectual property. The Oxford/MidCap Loan Agreement restricts our ability to incur additional indebtedness, pay dividends, pledge our intellectual property and engage in significant business transactions such as a change of control of Omeros. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. In addition, if we default under the Oxford/MidCap Loan Agreement, the lenders may have the right to accelerate all of our repayment obligations under the Oxford/MidCap Loan Agreement and to take control of our pledged assets, which include our cash, cash equivalents and short-term investments, potentially requiring us to renegotiate the Oxford/MidCap Loan Agreement on terms less favorable to us. 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/MidCap 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/MidCap 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/MidCap Loan Agreement, including but not limited to the lender concluding that a material adverse change has occurred as defined under the Oxford/MidCap 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.

Our agreements with Vulcan Inc. and its affiliate, which we refer to collectively as Vulcan, and the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or LSDF, include terms that may reduce the purchase price that a third party would be willing to pay for the GPCR program or for us in a change of control.

Under our GPCR funding agreement with Vulcan, if we decide to sell or assign all or substantially all of the assets in our GPCR program prior to the time that Vulcan has received $60.0 million from us under our agreement, Vulcan may require that the purchaser assume all of our rights and obligations pursuant to the agreement, including our obligation to pay tiered percentages of any net proceeds that we receive from the GPCR program. The term of the Vulcan agreement is at least 35 years. If, at our option, we elect to assign the LSDF agreement in connection with the sale of the GPCR program, a potential purchaser would also have to assume similar payment obligations to LSDF. Potential purchasers of our GPCR program may be less inclined to purchase the program because of these obligations. Further, even if they are willing to assume our rights and obligations, they may be unwilling to pay as much for our GPCR program as they would be without such requirement. In addition, if a transaction results in a change of control of Omeros, the acquiring party will be required to assume our rights and obligations under the Vulcan and LSDF agreements. As a result of these provisions, a party that wants to acquire us through a change of control may be less inclined to do so or not be willing to pay as much.

We have granted Vulcan a lien on all of our GPCR assets, excluding intellectual property, which provides Vulcan a right, senior to our shareholders, to receive proceeds generated from a liquidation of our GPCR assets as well as potentially limiting our operating and financial flexibility.

We have granted Vulcan a lien on all of our GPCR assets, excluding intellectual property, to secure our obligations under our agreement with Vulcan. This lien is, and will continue to be, junior to security interests we grant to third parties in connection with indebtedness for borrowed money. The lien will automatically be released once we have paid Vulcan or its affiliate $25.0 million out of net proceeds received from the GPCR program. If we default under our agreement with Vulcan, in certain circumstances Vulcan may, subject to the rights of any holders of senior security interests, take control of such pledged assets. We have also agreed with Vulcan not to grant any liens on our GPCR-related intellectual property related to our cellular redistribution assay, subject to specified exceptions. If we are liquidated, Vulcan's right to receive any payments then due under our agreement would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation of our GPCR program assets. Further, the junior lien and negative pledge on our intellectual property restrict our operating and financial flexibility, potentially limiting our ability to pursue business opportunities and making it more difficult for us to respond to changes in our business.

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.

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, 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.

We incur significant costs and demands on management as a result of complying with the laws and regulations affecting public companies.

We have incurred, and will continue to incur, significant costs associated with compliance with public company reporting and corporate governance requirements, including under the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, as well as rules implemented by the SEC and The Nasdaq Stock Market. The requirements of applicable SEC and Nasdaq rules and regulations may increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. We also expect that these rules and regulations may make it difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage than was previously available. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

We are required to make an assessment of the effectiveness of our internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Further, our independent registered public accounting firm has been engaged to express an opinion on the effectiveness of our internal control over financial reporting. If we are unable to comply with the requirements of Section 404, management may not be able to assess whether our internal control over financial reporting is effective, which may subject us to adverse regulatory consequences and could result in a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we fail to maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner or otherwise comply with the standards applicable to us as a public company. Any failure by us to provide the required financial information in a timely manner could materially and adversely impact our financial condition and the market value of our securities.

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 effect. 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 Industry

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

We may not achieve commercial success, particularly if our competitors 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. For example, compounding pharmacies or registered outsourcing facilities could seek to supply compounded versions of Omidria, which could have a material adverse effect on our business and financial condition, and enforcement of our intellectual property to address such activities may consume significant time and resources that could also have a material adverse effect on our business and financial condition. As a further example, other pharmaceutical companies, many with significantly greater resources than we have, are developing PDE10 inhibitors with the same mechanism of action as our product candidate OMS824, and these companies may be further along in development and have the resources to develop their product candidates at a faster rate than we can. In addition, we believe that other companies are attempting to find compounds that functionally interact with orphan GPCRs. If any of these companies are able to achieve this for a given orphan GPCR before we do, we may be unable to establish a commercially valuable intellectual property position around that orphan GPCR. 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, financial condition and results of operations.

The pharmaceutical industry is intensely competitive and many of our competitors have significantly more resources and experience, which may limit our commercial opportunities.

The pharmaceutical industry is intensely competitive in the markets in which we expect to compete. 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. Our competitors may:

- operate larger research and development programs, possess commercial-scale manufacturing operations or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to remain current with rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our product discovery process that we believe we derive from our research approach and proprietary technologies and programs.

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

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

conditions of approval, or the approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with Omidria or any of our other approved products, or failure to comply with regulatory requirements, may result in:

- restrictions on such products or manufacturing processes;
- withdrawal of the products from the market;
- voluntary or mandatory recalls;
- fines;
- suspension or withdrawal of regulatory approvals;
- product seizures; or
- injunctions or the imposition of civil or criminal penalties.

If we are slow or unable to adapt to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we may lose marketing approval for Omidria, or for our product candidates when and if any of them are approved.

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.

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 September 30, 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 various factors, some of which are beyond our control. These factors could include:

- failure of Omidria, or any of our product candidates if approved, to achieve commercial success;
- the pace of acceptance of Omidria by physicians, patients, third-party payers and other members of the medical community, or the timing and level of insurance coverage and reimbursement;
- FDA or foreign regulatory actions related to Omidria or any of our product candidates, including our programs evaluating OMS824 for the treatment of Huntington's disease and for the treatment of schizophrenia;
- our ability to partner in the EU with respect to Omidria;
- results from our clinical development programs, including the data from our ongoing clinical development programs evaluating Omidria, OMS721, OMS824, and PPARγ;
- failure of Fagron to manufacture and commercialize OMS103 successfully or in accordance with the terms of the OMS103 Agreement;
- announcements regarding the progress of our preclinical programs, including without limitation our GPCR program;
- quarterly variations in our results of operations, including potential product returns and timing of revenue recognition, or in those of our competitors;
- our ability to develop and market new and enhanced products on a timely basis;
- announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;
- third-party coverage and reimbursement policies;
- additions or departures of key personnel;

- commencement of, our involvement in and resolution of litigation;
- our ability to meet our repayment and other obligations under the Oxford/MidCap Loan Agreement;
- the inability of our contract manufacturers to provide us with adequate commercial supplies of Omidria and our product candidates;
- changes in governmental regulations or in the status of our regulatory approvals;
- changes in earnings estimates or recommendations by securities analysts or failure of our financial performance to meet estimates or guidance provided to the public;
- any major change in our board or management;
- the extent to which we raise funds by issuing equity or debt securities;
- general economic conditions and slow or negative growth of our markets; and
- political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various commercial, scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the commercialization of our product candidates may be delayed.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

We expect that we will continue to need additional capital in the future; however, such capital may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing shareholders would experience further dilution.

Although we expect that we will need additional capital in the future, we cannot be certain that it will be available to us on acceptable terms, if at all, when required. Disruptions in the global equity and credit markets may limit our ability to access capital. To the extent that we raise additional funds by issuing equity securities, our shareholders would experience dilution, which may be significant and could cause the market price of our common stock to decline significantly. Any debt financing, if available, may restrict our operations similar to the Oxford/MidCap Loan Agreement, or in other ways. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the commercialization of Omidria or the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. We also could be required to seek collaborators for one or more of our current or future 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 events could significantly harm our business and prospects and could cause our stock price to decline.

Future sales of shares by holders of outstanding warrants and options could cause our stock price to decline.

Approximately 9.5 million shares of common stock that are either subject to outstanding warrants or outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements. In addition, we also have approximately 1.7 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, and we have not generated any material revenue. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Additionally, under the Oxford/MidCap Loan Agreement, we have agreed not to pay any dividends so long as we have any outstanding obligations under the agreement. 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 6. EXHIBITS

Exhibit Number	Description
10.1††	First Amendment to Commercial Supply Agreement dated August 1, 2015 by and between Omeros Corporation and Hospira Worldwide, Inc.
10.2††	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
10.3	Fourth Amendment to Lease dated September 8, 2015 between Omeros Corporation and BMR-201 Elliott Avenue LLC
12.1	Ratio of Earnings to Fixed Charges
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

†† Portions of this exhibit are redacted in accordance with a request for confidential treatment.

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

Dated: November 9, 2015

/s/ Gregory A. Demopulos

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

Dated: November 9, 2015

/s/ Michael A. Jacobsen

Michael A. Jacobsen
Vice President, Finance, Chief Accounting Officer and Treasurer

EXHIBIT 10.1

CONFIDENTIAL TREATMENT REQUESTED under 17 C.F.R. § 200.80(b)(4) and 240.24b-2

FIRST AMENDMENT TO COMMERCIAL SUPPLY AGREEMENT

This First Amendment (**"Amendment"**) to the Commercial Supply Agreement is made effective as of this 1st day of August, 2015 (**"Amendment Effective Date"**), by and between Omeros Corporation (**"Omeros"**) and Hospira Worldwide, Inc. (**"Hospira"**). Each of Hospira and Omeros is referred to herein individually as a "**Party**" and together as the "**Parties**."

WHEREAS, Omeros and Hospira are Parties to that certain Commercial Supply Agreement, dated as of October 3, 2014 (the ***"Agreement"***), and

WHEREAS, the parties wish to amend the Agreement to reflect the Parties' mutual agreement to transfer manufacturing operations for the Product from Hospira's [†] facility to its facility at [†]; and to provide for additional an additional Product configuration under the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth in this First Amendment, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree that the Agreement is further amended as follows:

1. **Incorporation of the Agreement**. The Agreement is incorporated herein by this reference as though the same was set forth in its entirety. Except as specifically set forth herein, the Agreement shall remain in full force and effect and its provisions shall be binding on the parties hereto.

2. **Preamble**. The preamble of the Agreement is hereby amended change the definition of Hospira to "Hospira Worldwide, Inc. ("**Hospira**"). The following listed clauses are stricken to reflect the transfer of manufacturing operations from the Hospira [†] plant to the [†] facility [†]:

> "Hospira S.p.A., having its registered address at [†] (**"Hospira** [†]**"**) on behalf of its Affiliated corporation,"
>
> "For purposes of this Agreement, Hospira [†] and Hospira US shall be referred to collectively as "**Hospira**", unless the content requires otherwise."

3. **Definitions; References**. Certain defined terms are amended or replaced to the Agreement as indicated below. Otherwise, all capitalized terms which are not defined herein shall have the same meanings as set forth in the Agreement. References to numbered sections cited herein refer to specific sections of the Agreement, as amended.

The following existing definitions are hereby amended and replaced as follows:

(a) The definition of "**Business Day**" is hereby replaced in its entirety with the following:

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

““Business Day” means any day which is not a Saturday or Sunday or a bank or public holiday in Seattle, Washington, [†] or [†].”

(b) The definition of “**Facility**” is hereby replaced in its entirety with the following:

““**Facility**” means Hospira’s pharmaceutical manufacturing facility at [†], or for certain operations as specified in this Agreement, [†].”

(c) In the definition of **“Latent Defect”** the references to “the QP” are replaced by “Hospira’s quality representative.”

4. **Section 3.2**. - **Quality Control; Agreement and Certificates**

(a) In the first sentence, the reference to “Hospira’s Qualified Person(s) (**“QP”**)” is replaced by “Hospira’s quality representative.”

(b) The penultimate sentence is hereby amended to read as follows:

“Notwithstanding the foregoing, the Parties agree that for Product with a final destination in the European Union, Omeros may at its option employ the services of Hospira’s [†]-based QP’s or Third Party QPs to conduct the release testing of each such Batch, and in accordance with Section 3.3 shall determine whether such Batch is conforming.”

5. **Section 3.9.2 - Price Adjustments**. The penultimate sentence of Section 3.9.2 is hereby deleted and replaced by the following clause:

“Such increases shall not exceed the lesser of (a) [†], or (b) [†].”

6. **Section 3.9.3 - Taxes; VAT; User Fees** . Section 3.9.3 is deleted in its entirety an replaced with the following new clause:

“Taxes. Omeros will pay all federal, state, county or municipal sales or use tax, excise, customs charges, duties or similar charge, or any other tax assessment (other than that assessed against income or payments required to be made by Hospira as an employer), licence, fee or other charge lawfully assessed or charged on the manufacture, sale or transportation of the Product that Hospira manufactures, sell and delivers pursuant to this Agreement. In particular, Omeros will be responsible for and pay all Prescription Drug User (PDUFA) annual establishment fees with respect to the Product. For the avoidance of doubt, Omeros shall not be required to pay any PDUFA annual facility fees, which shall be Hospira’s sole and exclusive obligation. Omeros will provide Hospira with copies of any state tax exemption form

(s) if it intends to claim exemption for sales or use taxes in any state(s) where the Product is to be shipped."

7. **Section 3.9.4 - Payment Terms**. The first sentence of Section 3.9.4 is amended to read as follows:

"Except for specified payments to be made in [†] for work done at the Hospira [†] Facility, Omeros shall make payment of any undisputed portion of such invoices in [†] within thirty (30) days after Omeros' receipt of each such invoice, unless otherwise specifically set forth in this Agreement."

8. **Section 3.11.2 - Purchase Order Changes; Cancellation.** In the second sentence of Section 3.11.2, the reference to a [†] is hereby changed to stipulate a [†].

9. **Section 3.15 – Storage Fee**. The last sentence of Section 3.15 is hereby amended to read as follows:

"The fee shall be [†]."

10. **Section 3.16 - Shipments per Batch**. The second sentence of Section 3.16 is hereby amended to read as follows:

"Any additional shipments of Product per Batch requested shall be at a fee of [†] per shipment plus shipping costs."

11. **Section 5.6 - Regulatory Inspections**. The second sentence of Section 5.6 is amended as follows:

"Omeros agrees to offset Hospira's costs for each PAI inspection at the rate of [†] per PAI."

12. **Section 5.7 - Changes in Territory**. The last sentence of Section 5.7 is hereby amended to read as follows:

"Hospira shall be entitled to charge a fee of [†] for any additional pre-approval inspections of the Facility that may be required by relevant Regulatory Authorities."

13. **Section 12.6 – Notices**. Section 12.6 is hereby amended by replacing the notice information of Hospira Liscate with the following:

If to Hospira:

Hospira Worldwide, Inc.
275 North Field Drive

Lake Forest, Illinois 60045

Attention: V.P. Contract Manufacturing
Facsimile: (224) 212-3210

14. **EXHIBIT A – Additional Definitions**. Exhibit A is hereby amended by striking the following definitions from the Amendment table:

Defined Term	Section in which Defined
Hospira [†]	Premable
Hospira US	Preamble
VAT	3.9.3

15. **EXHIBIT B - Specifications**. Exhibit B is hereby amended by replacing the original Exhibit with Annex I

16. **EXHIBIT C – Stability Testing**. Exhibit C is hereby amended by deleting the existing table in its entirety and replacing it with the table included on Annex II, attached hereto.

17. **EXHIBIT D – Price**. Exhibit D is hereby amended by deleting the existing table in its entirety and replacing it with the table included on Annex III, attached hereto.

18. Except as expressly amended by this Amendment, the Agreement shall remain unchanged and continue in full force and effect as provided therein. This Amendment (including Annexes I, II and III attached hereto) and the Agreement constitute the complete, final and exclusive understanding and agreement of the parties with respect to the subject matter of the Agreement, and supersede any and all prior or contemporaneous negotiations, correspondence, understandings and agreements, whether oral or written, between the parties respecting the subject matter of the Agreement. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. In the event of a conflict between the terms of this Amendment and the terms of the Agreement, the terms of this Amendment shall prevail.

19. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK

SIGNATURE PAGE FOLLOWS

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

IN WITNESS THEREOF, the Parties have caused this Amendment to be duly executed as of the Amendment Effective Date.

OMEROS CORPORATION

By: /s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D.
Chairman & CEO

HOSPIRA WORLDWIDE, INC.

By: /s/ Karen Blair
Karen Blair
Vice President, One 2 One Contract Manufacturing Services

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ANNEX I

EXHIBIT B

Specifications

[†]

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ANNEX II

EXHIBIT C

Stability Tests

Stability Testing	Req.	Not Req.	N/A	Responsibility		Cost	Comment
				Hospira	Client		
Engineering batch stability		X					
Registration batch stability (Optional)	X			X		[†]	[†]
Annual Marketed Product stability	X			X		[†]	[†]
Total Cost:	[†]					[†]	
Payment:	**Mutually agreed upon yearly schedule**						
Timing:	**Per stability matrix**						

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ANNEX III

EXHIBIT D

Price

Commercial Product Pricing Table

[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
			[†]	[†]
[†]	[†]	[†]	[†]	[†]
			[†]	[†]
[†]	[†]	[†]	[†]	[†]
			[†]	[†]
[†]	[†]	[†]	[†]	[†]
		[†]		[†]
		[†]		[†]
		[†]		[†]

Product Assumptions:

- [†]
- Cost of two active ingredients (phenylephrine HCl, ketorolac tromethamine) are not included in quote and will be added as a pass through charge without mark-up
- API storage conditions – [†]
- Finished product storage conditions – [†]
- In-process and release testing to meet [†] standards
- [†].
- [†]
- [†].
- Drug product release testing to be performed by Hospira with issuance of a Certificate of Analysis to Omeros, with released product to have [†].
- A Quality Agreement must be executed prior to GMP batch production.

NOTE: Should any of these preliminary assumptions change during the course of the negotiation period or initial development work, Hospira reserves the right to adjust the price per unit to reflect true changes in costs.

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EXHIBIT 10.2

CONFIDENTIAL TREATMENT REQUESTED under 17 C.F.R. § 200.80(b)(4) and 240.24b-2

First Amendment to

Pharmaceutical Manufacturing and Supply Agreement

This is an Amendment (this "**Amendment**") to the Pharmaceutical Manufacturing and Supply Agreement dated **March 5, 2014** between DSM Pharmaceuticals, Inc. ("**DSM**") and Omeros Corporation ("**Omeros**") (the "**Master Agreement**"), and is entered into as of July 7, 2015 (the "**Amendment Effective Date**"). All initially capitalized terms in this Amendment shall have the same meaning as set forth in the Master Agreement unless otherwise defined herein.

Whereas, DSM's right and obligations under the Master Agreement were assigned to and assumed by Patheon Manufacturing Services LLC ("**Patheon**") as of May 31, 2014.

Whereas the Master Agreement provides for the manufacture of Omeros' Product OMS302, which has been approved by FDA as OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3%, pursuant to which Patheon has been providing fill and finish services for Product at Patheon's [†] facility in [†] ("**Patheon** [†] **Facility**") and labeling and packaging services for such Product at Patheon's [†] facility in [†] ("**Patheon** [†] **Facility**"), and Patheon intends to cease fill and finish manufacturing at the Patheon [†] Facility as of December 31, 2015, which is the end of the Initial Term of the Master Agreement (the "**Initial Term Expiration Date**").

Whereas Omeros and Patheon are working towards entry into a Master Manufacturing Services Agreement for fill and finish manufacture of Product at the Patheon [†] Facility, and Omeros and Patheon wish to provide for the labeling and packaging at the Patheon [†] Facility after the Initial Term Expiration Date of Product that has been filled and finished at the Patheon [†] Facility on or before the Initial Term Expiration Date.

Therefore Omeros and Patheon agree that the Master Agreement shall be hereby amended as follows:

Section 11.1 of the Master Agreement shall be revised to read as follows:

> 11.1 Term. Unless sooner terminated pursuant to the terms hereof or otherwise extended by mutual written agreement of the Parties, the term of this Agreement shall commence on the Effective Date and shall continue in force and effect until August 31, 2016 (the "Initial Term"), provided, however, that the Parties agree that DSM and its successors-in-interest shall have no obligation under this Agreement after December 31, 2015 to provide manufacturing, processing, purifying, formulating, or finishing Manufacturing services for Product at DSM's [†] facility located in [†] or at any other facility, but shall be obligated until August 31, 2016 only to provide packaging, labeling, holding, handling, storing, preparing for shipment, inspecting and quality control and stability testing Manufacturing services at DSM's [†] facility located in [†] for Product that was filled and finished prior to December 31, 2015 at DSM's [†] facility located in [†].

All other terms of the Master Agreement shall remain unchanged and in full force and effect.

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON MANUFACTURING SERVICES LLC

By: /s/ Andrew Crerar

Name: Andrew Crerar

Title: VP & GM Commercial Ops

OMEROS CORPORATION

By: /s/ Gregory A. Demopulos

Name: Gregory A. Demopulos, M.D.

Title: Chairman & CEO

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

EXHIBIT 10.3

FOURTH AMENDMENT TO LEASE

THIS FOURTH AMENDMENT TO LEASE (this "Amendment") is entered into as of this 8 day of September, 2015 (the "Fourth Amendment Execution Date"), by and between BMR-201 ELLIOTT AVENUE LLC, a Delaware limited liability company ("Landlord"), and OMEROS CORPORATION, a Washington corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant are parties to that certain Lease dated as of January 27, 2012 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of November 5, 2012, that certain Second Amendment to Lease dated as of November 16, 2012 (the "Second Amendment") and that certain Third Amendment to Lease dated as of October 16, 2013 (collectively, and as the same may have been further amended, amended and restated, supplemented or modified from time to time, the "Existing Lease"), whereby Tenant leases certain premises (the "Existing Premises") from Landlord at 201 Elliott Avenue West in Seattle, Washington (the "Building"), including certain space within the Building's vivarium (such portion of the Building's vivarium currently leased to Tenant, the "Tenant's Existing Vivarium Space");

B. WHEREAS, Tenant desires to lease additional premises from Landlord in the Building's vivarium; and

C. WHEREAS, Landlord and Tenant desire to modify and amend the Existing Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Definitions. For purposes of this Amendment, capitalized terms shall have the meanings ascribed to them in the Existing Lease unless otherwise defined herein. The Existing Lease, as amended by this Amendment, is referred to collectively herein as the "Lease." From and after the date hereof, the term "Lease," as used in the Existing Lease, shall mean the Existing Lease, as amended by this Amendment.

2. Second Additional Vivarium Premises. Effective as of the Fourth Amendment Execution Date, Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord, approximately two thousand two hundred forty-four (2,244) additional square feet of Rentable Area located in the Vivarium, as shown on Exhibit A attached hereto (the "Second Additional Vivarium Premises"), for use by Tenant in accordance with the Permitted Use and in accordance with all other terms and conditions of the Lease. From and after the Fourth Amendment Execution Date, the term "Premises," as used in the Lease shall mean the Existing Premises plus the Second Additional Vivarium Premises, and the term "Tenant's Vivarium Space," as used in the Existing Lease, shall mean the Tenant's Existing Vivarium Space plus the Second Additional Vivarium Premises.

3. Second Additional Vivarium Term. The term of the Lease with respect to the Second Additional Vivarium Premises (as the same may be earlier terminated in accordance with the Lease, the "Second Additional Vivarium Term") shall commence on the Fourth Amendment Execution Date and end on the Term Expiration Date. Failure by Tenant to obtain validation by any medical review board or other similar governmental licensing of the Second Additional Vivarium Premises required for the Permitted Use by Tenant shall not serve to extend the commencement of the Second Additional Vivarium Term.

4. Condition of Second Additional Vivarium Premises. Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the Second Additional Vivarium Premises or with respect to the suitability of the Second Additional Vivarium Premises for the conduct of Tenant's business. Tenant acknowledges that (a) it is fully familiar with the condition of the Second Additional Vivarium Premises and agrees to take the same in its condition "as is" as of the Fourth Amendment Execution Date and (b) Landlord shall have no obligation to alter, repair or otherwise prepare the Second Additional Vivarium Premises for Tenant's occupancy or to pay for or construct any improvements to the Second Additional Vivarium Premises. Tenant's taking of possession of the Second Additional Vivarium Premises shall, except as otherwise agreed to in writing by Landlord and Tenant, conclusively establish that the Second Additional Vivarium Premises were at such time in good, sanitary and satisfactory condition and repair.

5. Base Rent. Tenant shall pay to Landlord as Base Rent for the Second Additional Vivarium Premises, commencing on the Fourth Amendment Execution Date, the amounts set forth on Exhibit B attached hereto.

6. Pro Rata Share. Tenant's Pro Rata Share of the Project with respect to the Second Additional Vivarium Premises shall be 1.48%, and, therefore, commencing as of the Fourth Amendment Execution Date, Tenant's Pro Rata Share of the Project for the entire Premises (i.e., the Existing Premises plus the Second Additional Vivarium Premises) shall be 56.40%.

7. Termination Option. Section 3.1 of the Second Amendment shall continue to apply to the Additional Vivarium Premises (as defined in the Second Amendment). Notwithstanding anything to the contrary in the Lease, Tenant shall have the right to terminate the Lease, but only with respect to the Second Additional Vivarium Premises (and no less than all of the Second Additional Vivarium Premises), by providing written notice (the "Second Additional Vivarium Termination Notice") to Landlord at least sixty (60) days prior to Tenant's desired termination date (the "Second Additional Vivarium Termination Date"), which Second Additional Vivarium Termination Date shall be set forth in the Second Additional Vivarium Termination Notice. Subject to (a) Landlord's timely receipt of the Second Additional Vivarium Termination Notice and (b) Tenant surrendering the Second Additional Vivarium Premises in the condition required under the Lease (including, without limitation, Section 18.2 and Article 26 of the Lease), then, as of the Second Additional Vivarium Termination Date, the Lease with respect to the Second Additional Vivarium Premises shall terminate and be of no further force or effect, and Landlord and Tenant shall be relieved of their respective obligations under the Lease with respect to the Second Additional Vivarium Premises from and after the Second Additional Vivarium Termination Date, except with

respect to those obligations set forth in the Lease that expressly survive the expiration or earlier termination thereof, including payment by Tenant of all amounts owed by Tenant pursuant to the Lease with respect to the Second Additional Vivarium Premises for the period up to and including the Second Additional Vivarium Termination Date. The termination right granted to Tenant pursuant to this Section shall automatically terminate and be of no further force or effect in the event that (y) Tenant assigns, subleases or otherwise Transfers the Second Additional Vivarium Premises or any portion thereof to other entities or persons, other than in connection with an Exempt Transfer (or in connection with any sublease approved by Landlord pursuant to Article 29 of the Original Lease), or (z) Tenant's right to possession of the Second Additional Vivarium Premises has previously been terminated. The termination right granted to Tenant pursuant to this Section is personal to Tenant and any Permitted Transferees, and may not be exercised by any other assignee, sublessee or transferee of Tenant's or a Permitted Transferee's interest in the Lease.

8. Broker. Tenant represents and warrants that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment and agrees to indemnify, save, defend and hold harmless the Landlord Indemnitees for, from and against any and all cost or liability for compensation claimed by any such broker or agent employed or engaged by it or claiming to have been employed or engaged by it

9. No Default. Tenant represents, warrants and covenants that, to the best of Tenant's knowledge, Landlord and Tenant are not in default of any of their respective obligations under the Existing Lease and no event has occurred that, with the passage of time or the giving of notice (or both) would constitute a default by either Landlord or Tenant thereunder.

10. Notices. Tenant confirms that, notwithstanding anything in the Lease to the contrary, notices delivered to Tenant pursuant to the Lease should be sent to:

Omeros Corporation
201 Elliott Avenue West
Seattle, Washington 98119
Attn: Chief Executive Officer
E-mail: gdemopulos@omeros.com;

with a copy to:

Omeros Corporation
201 Elliott Avenue West
Seattle, Washington 98119
Attn: General Counsel
E-mail: mkelbon@omeros.com.

11. Effect of Amendment. Except as modified by this Amendment, the Existing Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. In the event of any conflict between the terms contained in this Amendment and the Existing Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties.

12. Successors and Assigns. Each of the covenants, conditions and agreements contained in this Amendment shall inure to the benefit of and shall apply to and be binding upon the parties hereto and their respective heirs, legatees, devisees, executors, administrators and permitted successors and assigns and sublessees. Nothing in this section shall in any way alter the provisions of the Lease restricting assignment or subletting.

13. Miscellaneous. This Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Amendment are inserted and included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease, lease amendment or otherwise until execution by and delivery to both Landlord and Tenant.

14. Authority. Tenant guarantees, warrants and represents that the individual or individuals signing this Amendment have the power, authority and legal capacity to sign this Amendment on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed.

15. Counterparts; Facsimile and PDF Signatures. This Amendment may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document. A facsimile or portable document format (PDF) signature on this Amendment shall be equivalent to, and have the same force and effect as, an original signature.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the date and year first above written.

LANDLORD:

BMR-201 ELLIOTT AVENUE LLC,
a Delaware limited liability company

By: /s/ Kevin M. Simonsen
Name: Kevin M. Simonsen
Title: Sr. VP, Real Estate Legal

TENANT:

OMEROS CORPORATION,
a Washington corporation

By: /s/ Gregory A. Demopulos
Name: Gregory A. Demopulos, M.D.
Title: Chairman and CEO

EXHIBIT A

SECOND ADDITIONAL VIVARIUM PREMISES

EXHIBIT B

BASE RENT FOR SECOND ADDITIONAL VIVARIUM PREMISES

Dates	Square Feet of Rentable Area	Annual Base Rent per Square Foot of Rentable Area	Monthly Base Rent	Annual Base Rent
Fourth Amendment Execution Date - November 15, 2015	2,244	$63.65	$11,902.55	$142,830.60
November 16, 2015 - November 15, 2016	2,244	$65.56	$12,259.72	$147,116.64
November 16, 2016 - November 15, 2017	2,244	$67.53	$12,628.11	$151,537.32
November 16, 2017 - November 15, 2018	2,244	$69.56	$13,007.72	$156,092.64
November 16, 2018 - November 15, 2019	2,244	$71.64	$13,396.68	$160,760.16
November 16, 2019 - November 15, 2020	2,244	$73.79	$13,798.73	$165,584.76
November 16, 2020 - November 15, 2021	2,244	$76.01	$14,213.87	$170,566.44
November 16, 2021 - November 15, 2022	2,244	$78.29	$14,640.23	$175,682.76
November 16, 2022 - November 15, 2023	2,244	$80.63	$15,077.81	$180,933.72
November 16, 2023 - November 15, 2024	2,244	$83.05	$15,530.35	$186,364.20
November 16, 2024 - November 15, 2025	2,244	$85.55	$15,997.85	$191,974.20
November 16, 2025 - November 15, 2026	2,244	$88.11	$16,476.57	$197,718.84
November 16, 2026 - November 15, 2027	2,244	$90.76	$16,972.12	$203,665.44

EXHIBIT 12.1

Omeros Corporation
Computation of Deficiency in the Coverage of Fixed Charges by Earnings Before Fixed Charges

	For the nine months ended September 30, 2015	Year Ended December 31, 2014	2013	2012	2011	2010
	(in thousands)			(in thousands)		
Earnings before fixed charges:						
Loss from continuing operations before income taxes	$ (55,270)	$ (73,673)	$ (39,796)	$ (38,444)	$ (28,546)	$ (29,251)
Add fixed charges	5,327	6,824	5,621	2,305	2,144	2,104
Add amortization of capitalized interest	—	—	—	—	—	—
Add distributed income of equity investees	—	—	—	—	—	—
Subtract capitalized interest	—	—	—	—	—	—
Loss before fixed charges	$ (49,943)	$ (66,849)	$ (34,175)	$ (36,139)	$ (26,402)	$ (27,147)
Fixed Charges:						
Interest expense	$ 2,104	$ 2,710	$ 1,865	$ 1,355	$ 1,532	$ 1,328
Amortization of debt expense and loss from extinguishment of debt	658	759	502	374	352	503
Estimate of interest expense within rental expense	2,565	3,355	3,254	576	260	273
Preference security dividend requirements of consolidated subsidiaries	—	—	—	—	—	—
Total fixed charges	$ 5,327	$ 6,824	$ 5,621	$ 2,305	$ 2,144	$ 2,104
Deficiency of earnings available to cover fixed charges	(55,270)	$ (73,673)	$ (39,796)	$ (38,444)	$ (28,546)	$ (29,251)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gregory A. Demopulos, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Omeros Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 9, 2015

/s/ Gregory A. Demopulos

Gregory A. Demopulos, M.D.
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael A. Jacobsen, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Omeros Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 9, 2015

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer

Exhibit 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

In connection with the Quarterly Report on Form 10-Q of Omeros Corporation (the "Company") for the quarter ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Dated: November 9, 2015

/s/ Gregory A. Demopulos

Gregory A. Demopulos, M.D.
Principal Executive Officer

Exhibit 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

In connection with the Quarterly Report on Form 10-Q of Omeros Corporation (the "Company") for the quarter ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Dated: November 9, 2015

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer