OMEROS CORP
Form 10-Q
November 10, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

or

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

For the transition period from to

Commission file number: 001-34475

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

Washington (State or other jurisdiction of incorporation or organization)	91-1663741 (I.R.S. Employer Identification Number)
201 Elliott Avenue West Seattle, Washington (Address of principal executive offices) (206) 676-5000 (Registrant's telephone number, including area code)	98119 (Zip 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 x No ¨

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

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

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

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

As of November 6, 2014, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 34,075,924.

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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," "shoul similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

- our anticipation that we will begin U.S. commercial sales of Omidria™ in early 2015;
- our ability to receive regulatory approval for our Marketing Authorisation Application, or MAA, for OMS302, or Omidria, in the European Union, or EU;
- our expectation of receiving an opinion on the MAA from the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, in the fourth quarter of 2014;
- our ability to partner in Europe and our anticipation that we will initiate marketing and sales of Omidria in the EU in the first half of 2015, assuming approval of our MAA for Omidria and partnering in Europe;
- our plans for sales, marketing and distribution of Omidria in the U.S. and for partnering, sales, marketing and distribution in the EU and other international territories;
- our expectation that additional sales representatives will be hired, trained and in the field by the end of January 2015;
- our ability to successfully complete our Phase 2 clinical trials for OMS824 and OMS721;
- our ability to recommence active enrollment in our Phase 2 clinical trial of OMS824 in Huntington's disease or initiate further clinical studies in either our OMS824 Huntington's or schizophrenia programs;
- our ability to initiate post-marketing studies for Omidria and additional clinical trials for OMS103, should they be necessary;
- whether there may be an opportunity to have OMS103 produced and commercialized by a registered outsourcing facility;
- our expectations regarding the clinical, therapeutic and competitive benefits of Omidria and our product candidates;
- our anticipated future sales from Omidria 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 anticipation that we will rely on contract manufacturers to develop and manufacture our product candidates and to manufacture Omidria for commercial sale;
- our ability to enter into acceptable arrangements with potential corporate partners;
- whether pediatric studies may afford Omidria an additional six months of exclusivity;
- our expectations about the commercial competition that Omidria and our product candidates may face;
- our expected financial position, performance, growth, expenses, magnitude of net losses and availability of resources;
- 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; and
- our estimates regarding our future net losses, revenues, research and development expenses and selling, general and administrative expenses.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part II of this Quarterly Report on Form 10-Q under the heading "Risk Factors" and in our other filings with the Securities and Exchange Commission. Given these risks, uncertainties and other factors, actual results or developments anticipated 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. These forward-looking

statements 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 law, we assume no obligation to update these forward-looking statements, or to

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update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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PART I—FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
OMEROS CORPORATION
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	September 30, 2014 (unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 750	$ 1,384
Short-term investments	21,030	12,717
Grant and other receivables	381	379
Prepaid expenses	1,052	251
Other current assets	148	86
Total current assets	23,361	14,817
Property and equipment, net	846	939
Restricted cash	679	679
Other assets	408	100
Total assets	$ 25,294	$ 16,535
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 4,156	$ 2,329
Accrued expenses	6,250	3,944
Current portion of notes payable, net of discount	3,991	5,600
Total current liabilities	14,397	11,873
Notes payable, net of current portion and discount	28,551	14,898
Deferred rent	8,935	8,148
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Preferred stock, par value $0.01 per share: Authorized shares—20,000,000 at September 30, 2014 (unaudited) and December 31, 2013;		
Issued and outstanding shares—none	—	—
Common stock, par value $0.01 per share: Authorized shares—150,000,000 at September 30, 2014 (unaudited) and December 31, 2013;		
Issued and outstanding shares—34,022,145 and 30,359,508 at September 30, 2014 (unaudited) and December 31, 2013, respectively	340	304
Additional paid-in capital	280,404	235,685
Accumulated deficit	(307,333)	(254,373)
Total shareholders' deficit	(26,589)	(18,384)
Total liabilities and shareholders' equity	$ 25,294	$ 16,535

See notes to consolidated financial statements

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OMEROS CORPORATION
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,	
	2014	2013	2014	2013
Revenue	$214	$196	$359	$1,431
Operating expenses:				
Research and development	11,772	9,420	36,196	26,111
Selling, general and administrative	5,574	4,210	14,196	11,934
Total operating expenses	17,346	13,630	50,392	38,045
Loss from operations	(17,132)	(13,434)	(50,033)	(36,614)
Investment income	3	2	10	10
Interest expense	(944)	(592)	(2,555)	(1,768)
Other income (expense), net	(254)	154	(382)	421
Net loss	$(18,327)	$(13,870)	$(52,960)	$(37,951)
Comprehensive loss	$(18,327)	$(13,870)	$(52,960)	$(37,951)
Basic and diluted net loss per share	$(0.54)	$(0.46)	$(1.61)	$(1.36)
Weighted-average shares used to compute basic and diluted net loss per share	34,005,642	29,844,507	32,945,346	27,984,133

See notes to consolidated financial statements

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OMEROS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(unaudited)

	Nine Months Ended September 30,	
	2014	2013
Operating activities:		
Net loss	$(52,960)	$(37,951)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of assets	(9)	—
Depreciation and amortization	246	222
Stock-based compensation expense	5,083	4,364
Non-cash interest expense	532	371
Warrant modification expense	863	41
Changes in operating assets and liabilities:		
Grant and other receivables	(2)	1,053
Prepaid expenses and other current and noncurrent assets	(842)	31
Accounts payable and accrued expenses	3,949	453
Deferred revenue	—	(970)
Deferred rent	787	2,987
Net cash used in operating activities	(42,353)	(29,399)
Investing activities:		
Purchases and sales of property and equipment, net	(12)	(137)
Purchases of investments	(58,847)	(22,963)
Proceeds from the sale and maturities of investments	50,534	35,945
Net cash (used in) provided by investing activities	(8,325)	12,845
Financing activities:		
Proceeds from issuance of common stock, net of offering costs	37,754	16,120
Net proceeds from borrowings under notes payable	12,699	—
Payments on notes payable	(1,464)	—
Proceeds from issuance of common stock upon exercise of stock options & warrants	1,055	64
Net cash provided by financing activities	50,044	16,184
Net decrease in cash and cash equivalents	(634)	(370)
Cash and cash equivalents at beginning of period	1,384	1,520
Cash and cash equivalents at end of period	$750	$1,150
Supplemental cash flow information		
Cash paid for interest	$1,931	$1,243
Reduction of equipment cost basis due to assets purchased with grant funding	$40	$—

See notes to consolidated financial statements

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OMEROS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Our PharmacoSurgery® platform, designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures, is based on low-dose combinations of 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 have six clinical-stage development programs in our pipeline, which also includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor (GPCR) drug targets and the other used to generate antibodies.

Derived from our proprietary PharmacoSurgery platform, our first drug product Omidria™ (phenylephrine and ketorolac injection) 1%/0.3% was approved by the U.S. Food and Drug Administration (FDA) on May 30, 2014 for use during cataract surgery or intraocular lens replacement (ILR) to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. We began calling on ophthalmic surgeons and their staff in the U.S. in August 2014 regarding Omidria. In October 2014, we were granted transitional pass-through reimbursement status from the Centers for Medicare and Medicaid Services (CMS) for Omidria, effective January 1, 2015. Pass-through status allows for separate payment for new drugs and other medical technologies that meet specific clinical-value and cost requirements. We expect pass-through to remain in effect for a period of two to three years from the January 1, 2015 effective date, after which time CMS will make a new reimbursement determination. We have submitted for Omidria a wholesale acquisition cost of $465 per single-use vial. We expect to begin selling Omidria in the U.S. in early 2015.

In September 2013, we submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Omidria. Marketing and sales of Omidria in the European Union (EU) are subject to approval of our MAA and, most likely, entering into a partnership for European marketing and distribution. In addition to the EU, we plan to enter into one or more partnerships for the marketing and distribution of Omidria in other international territories. For Omidria and each of our product candidates and our programs, we have retained all manufacturing, marketing and distribution rights.

Basis of Presentation

Our consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions between and among our subsidiaries have been eliminated. The accompanying unaudited 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, 2014 and for the three and nine months ended September 30, 2014 and 2013 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Consolidated Balance Sheet at December 31, 2013 has been derived from audited financial statements but does not include all of the information and footnotes required by GAAP.

The accompanying unaudited consolidated financial statements and notes to 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, 2013 filed with the Securities and Exchange Commission (SEC) on March 13, 2014.

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.

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Liquidity and Capital Resources

As of September 30, 2014, we had $21.8 million in cash, cash equivalents and short-term investments. We believe that our existing cash, cash equivalents and short-term investments, together with anticipated future sales from Omidria and capital that we may be able to raise through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales, 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. Corporate partnerships, public or private equity sales, additional debt financings, corporate collaboration and licensing arrangements or asset sales may not be available on terms that are acceptable to us, if at all, and any further equity financing would dilute the ownership of our existing shareholders. If we are unable to raise capital as and when needed, such failure would have a significant negative impact on our financial condition.

Inventory

Inventory is stated at the lower of cost or market. Capitalization of costs as inventory begins when the product has received regulatory approval in the U.S. or the EU. We expense inventory costs related to product candidates as research and development expenses prior to regulatory approval in the respective territory. For Omidria, capitalization of costs as inventory began upon U.S. regulatory approval on May 30, 2014.

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 August 2014, the Financial Accounting Standards Board issued Accounting Standards Update, or 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 period 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 do not expect the adoption of this guidance to have any impact on our financial position, results of operations or cash flows.

In May 2014, the Financial Accounting Standards Board 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. This standard is effective for interim and annual periods beginning after December 15, 2016 and cannot be adopted before that effective date. We are currently evaluating the impact 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, 2014 and 2013 were computed based on the shares of common stock outstanding during the respective periods. Potentially dilutive securities excluded from the diluted loss per share calculation are as follows:

	September 30,	
	2014	2013
Outstanding options to purchase common stock	6,779,998	6,909,332
Warrants to purchase common stock	604,327	609,016
Total	7,384,325	7,518,348

Note 3—Cash, Cash Equivalents and Investments

As of September 30, 2014 and December 31, 2013, all investments are classified as short-term and available-for-sale on the accompanying Consolidated Balance Sheets. We did not own any securities with unrealized loss positions as of September 30, 2014 or December 31, 2013. Investment income consists primarily of interest income.

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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 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, 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	21,030	—	—	21,030
Total	$21,709	$—	$—	$21,709

	December 31, 2013			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as cash equivalents	$213	$—	$—	$213
Money-market funds classified as non-current restricted cash	679	—	—	679
Money-market funds classified as short-term investments	12,717	—	—	12,717
Total	$13,609	$—	$—	$13,609

Cash held in demand deposit accounts of $750,000 and $1.2 million is excluded from our fair-value hierarchy disclosure as of September 30, 2014 and December 31, 2013, respectively. There were no unrealized gains and losses associated with our short-term investments as of September 30, 2014 or December 31, 2013. The carrying amounts reported in the accompanying Consolidated Balance Sheets for grant and other 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, 2014	December 31, 2013
	(In thousands)	
Contract research	$1,746	$858
Consulting & professional fees	1,536	649
Employee compensation	1,403	1,346
Clinical trials	949	596

Other accruals	616	495
Total accrued liabilities	$6,250	$3,944

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Note 6—Notes Payable

In March 2014, we entered into a new 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. 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 all loan initiation costs including a $160,000 upfront loan initiation fee and lenders' legal costs, we received $12.7 million in net proceeds. The Oxford/MidCap Loan Agreement provides for monthly 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 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 prepayment fee 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 incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, pledge our intellectual property or repurchase stock. Additionally, the Oxford/MidCap Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breach, occurrence of a material adverse effect (MAE, as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgment defaults and a change 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.

MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our inability to repay any portion of the loans in accordance with the terms of the Oxford/MidCap Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the enforceability of any material provision of the Oxford/MidCap Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce their rights and remedies under the Oxford/MidCap Loan Agreement or related agreements.

We accounted for the Oxford/MidCap Loan Agreement as a debt modification and, accordingly, the remaining unamortized debt issuance costs of $103,000 associated with the then outstanding loan with Oxford and the debt issuance costs of $244,000 associated with the Oxford/MidCap Loan Agreement are being amortized to interest expense using the effective interest method through the March 1, 2018 Oxford/MidCap Loan Agreement maturity date. Additionally, the $2.2 million maturity fee, which is treated as a debt discount, is being amortized to interest expense using the effective-interest method through March 1, 2018.

As of September 30, 2014, the remaining unamortized discount and debt issuance costs associated with the debt were $1.9 million and $284,000, respectively.

Note 7—Revenue

Revenue recognized from grants and other sources is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Small Business Innovative Research Grants	$214	$196	$359	$461
Vulcan Inc.	—	—	—	970
Total revenue	$214	$196	$359	$1,431

We have periodically received Small Business Innovative Research (SBIR) grants from the National Institutes of Health (NIH), which are used to support the research and development of our product candidates. We recorded revenue related to these grants of $214,000 and $196,000 for the three months ended September 30, 2014 and 2013, respectively, and $359,000 and $461,000 for the nine months ended September 30, 2014 and 2013, respectively. We recorded cost reductions to property and equipment due to assets being purchased with grant funding of $40,000 and $0 for the three and nine months ended September

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30, 2014 and 2013, respectively. As of September 30, 2014, $785,000 of potential revenue remained available under these grants, if qualifying research is performed.

In October 2010, we entered into a platform development funding agreement with Vulcan Inc. and its affiliate (collectively, Vulcan) pursuant to which we received $20.0 million for our G protein-coupled receptor (GPCR) program. Of the funds received, $8.2 million was recorded as deferred revenue. The remaining deferred revenue of $970,000 was recognized as revenue during the first quarter of 2013.

Note 8—Commitments and Contingencies

Real Estate Obligations

We lease our office and laboratory space in The Omeros Building under a lease agreement with BMR-201 Elliott Avenue LLC (BMR). 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, 2014, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately $59.4 million. The deferred rent balance relates to rent deferrals since the inception of our lease. Deferred rent is being amortized to research and development and selling, general and administrative expense on a straight-line basis through the term of the lease.

Contracts

In June 2014, we entered into an agreement with Ventiv Commercial Services, LLC (inVentiv) for field sales representatives and related sales operation services for the U.S. commercial launch of Omidria. As of September 30, 2014, we had a monthly fee of approximately $300,000, which began in August 2014. 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 any time subsequent to January 2016.

In October 2014, we entered into an amendment to the agreement with inVentiv for additional sales representatives in the U.S. Under the terms of the amendment, our total monthly fee will increase to approximately $630,000 upon inVentiv providing additional sales representatives, which is expected in January 2015, and will continue through January 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, 2014, we had a firm purchase commitment requiring payment of approximately $519,000.

In October 2014, we entered into a non-exclusive agreement with Hospira S.p.A and Hospira Worldwide, Inc. (together, “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 at Hospira, we provide monthly rolling forecasts that will be used to calculate our firm purchase commitment. We have not commenced commercial manufacturing of Omidria at Hospira and, therefore, do not currently have any firm purchase commitments under this agreement.

Development Milestones and Product Royalties

We have retained worldwide commercial rights to Omidria and all of our product candidates in our clinical and preclinical programs. 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 2013 Annual Report on Form 10-K filed with the SEC on March 13, 2014.

During the first quarter of 2014, we incurred a milestone payment of $200,000 to Helion Biotech ApS (Helion) related to the filing of an Investigational New Drug Application (IND) with the FDA for our mannan-binding lectin-associated serine protease-2 (MASP-2) program.

Other

In the first quarter of 2013, we recorded $900,000 as selling, general and administrative expense in connection with previously awarded NIH grants.

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Note 9—Shareholders' Equity

Common Stock

Public Offering - 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, 2014, which have a weighted average exercise price of $23.94:

Outstanding At September 30, 2014	Expiration Date	Exercise Price
192,789	March 29, 2015	$12.25
133,333	October 21, 2015	20.00
133,333	October 21, 2015	30.00
133,333	October 21, 2015	40.00
11,539	April 26, 2015	9.13
604,327		

On March 28, 2014, we extended to September 29, 2014 the expiration dates of warrants to purchase 197,478 shares of our common stock at an exercise price of $12.25 per share that had been due to expire on March 29, 2014. We evaluated the fair value of the warrants before and after the modifications and recorded the $452,000 change in fair value as other expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the three months ended March 31, 2014.

During September 2014, warrants associated with a total of 4,689 shares were exercised by the warrant holders resulting in the issuance of 3,305 shares of our common stock. Of that amount, 3,088 shares were issued upon cash exercise of warrants, pursuant to which we received proceeds of $37,828, and the remainder were issued pursuant to cashless net exercise provisions in the warrants.

On September 28, 2014, we extended to March 29, 2015 the expiration date of the remaining warrants to purchase 192,789 shares of our common stock that had been due to expire on September 29, 2014. We evaluated the fair value of the warrants before and after the modifications and recorded the $411,000 change in fair value as other expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the three months ended September 30, 2014. Considering the extensions on March 28 and September 28, 2014, the total other expense recorded in the Consolidated Statement of Operations and Comprehensive Loss for the nine months ended September 30, 2014 was $863,000.

In October 2010, in connection with the Vulcan agreement, we issued to Vulcan three warrants to purchase our common stock, each exercisable for 133,333 shares, with exercise prices of $20, $30 and $40 per share, respectively.

Note 10—Stock-Based Compensation

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

On January 1, 2014, in accordance with provisions of the 2008 Plan, the authorized shares available for grant under the 2008 Plan were increased by 1,517,975 shares. As of September 30, 2014, a total of 8,741,276 shares were reserved for issuance under our stock plans, of which 1,961,278 were available for future grants under the 2008 Plan.

In October 2014, in connection with our annual employee review process, we granted qualified employees options to purchase approximately 1.2 million shares of our common stock with an exercise price of $11.58.

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

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Estimated weighted-average fair value	$10.18	$6.77	$8.39	$6.73
Weighted-average assumptions				
Expected volatility	70%	88%	82%	87%
Expected term, in years	6.1	5.8	5.9	5.8
Risk-free interest rate	1.95%	1.66%	1.90%	1.65%
Expected dividend yield	—%	—%	—%	—%

Stock-based compensation expense has been reported in our Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Research and development	$879	$1,371	$2,791	$2,518
Selling, general and administrative	786	840	2,292	1,846
Total	$1,665	$2,211	$5,083	$4,364

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, 2013	6,969,303	$6.38		
Granted	184,250	12.00		
Exercised	(159,332)	6.39		
Forfeited	(214,223)	9.82		
Balance at September 30, 2014	6,779,998	$6.42	6.46	$42,797
Vested and expected to vest at September 30, 2014	6,577,603	$6.32	6.39	$42,141
Exercisable at September 30, 2014	4,755,993	$5.12	5.54	$36,147

At September 30, 2014, there were 2,024,005 unvested options outstanding that will vest over a weighted-average period of 2.0 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these options is $11.1 million.

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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 small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Our PharmacoSurgery® platform, designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures, is based on low-dose combinations of U.S. Food and Drug Administration, 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 have six clinical-stage development programs in our pipeline, which also 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 our first drug product Omidria™ (phenylephrine and ketorolac injection) 1%/0.3% and each of our product candidates and our programs, we have retained all manufacturing, marketing and distribution rights.

Products, Product Candidates and Development Programs

Products

Derived from our proprietary PharmacoSurgery platform, Omidria was approved by the FDA on May 30, 2014 for use during cataract surgery or intraocular lens replacement, or ILR, to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. Our U.S. marketing and sales leadership, including our national and regional sales managers, have been hired and our initial group of 20 contract field sales representatives, solely dedicated to Omeros, began calling on ophthalmic surgeons and their staff in August 2014. We are in the process of recruiting an additional 20 field sales representatives and expect them to be hired, trained and deployed by the end of January 2015. In October 2014 we were granted transitional pass-through reimbursement status from the Centers for Medicare and Medicaid Services, or CMS, for Omidria, effective January 1, 2015. Pass-through status allows for separate payment for new drugs and other medical technologies that meet specific clinical-value and cost requirements. We expect pass-through to remain in effect for a period of two to three years from the January 1, 2015 effective date, after which time CMS will make a new reimbursement determination. We have submitted for Omidria a wholesale acquisition cost, or WAC, of $465 per single-use vial. We expect to begin selling Omidria in the U.S. in early 2015.

In the European Union, or EU, we submitted a Marketing Authorisation Application, or MAA, to the European Medicines Agency, or EMA, in September 2013 seeking authorization to permit us to market and sell Omidria in the EU for use in patients undergoing ILR. In October 2013, the MAA for Omidria was validated by the EMA and we expect to receive an opinion on the MAA from the EMA's Committee for Medicinal Products for Human Use, or CHMP, the scientific committee of the EMA, in the fourth quarter of 2014. In the EU and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria. Assuming approval of our MAA for Omidria and partnering in Europe, we anticipate the initiation of EU marketing and sales of Omidria in the first half of 2015.

In addition, we have discussed with the FDA and EMA the design for pediatric studies for Omidria. In 2014 we initiated a pediatric study for Omidria in the U.S., and we have begun enrolling in this study. If this study is successfully completed according to the FDA's written request, Omidria would be eligible for an additional six months of marketing exclusivity in the U.S.

Product Candidates

In our pipeline we have a series of development programs targeting pain, inflammation, coagulopathies and disorders of the central nervous system, including the following six clinical-stage programs: (1) our lead MASP-2 antibody OMS721, which is in a Phase 2 clinical program in patients with thrombotic microangiopathies, or TMAs, (2) our Phase 2 program evaluating our lead phosphodiesterase 10, or PDE10, inhibitor OMS824 for the treatment of

Huntington's disease, which is in a Phase 2 clinical trial that is currently suspended pending further evaluation of an observation from a nonclinical study in rats, (3) our Phase 2 program evaluating OMS824 for the treatment of schizophrenia, which is not in an active clinical trial, (4) our PharmacoSurgery product candidate OMS103 for reducing inflammatory pain following arthroscopic partial meniscectomy, which has completed one Phase 3 trial in patients undergoing this procedure, (5) our PPAR program, in which three Phase 2 clinical trials are being conducted by our collaborators to evaluate a PPAR agonist, alone or in combination with other agents,

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for their effects on smoking, as well as in the abuse liability of oxycodone or heroin and (6) our PharmacoSurgery product candidate OMS201 for use during urological procedures, including uroendoscopic procedures, which completed a Phase 1/Phase 2 clinical trial in 2010 and is not currently in active clinical trials. Of these clinical programs, we currently are focused on OMS721, OMS824, and OMS103.

Our IND application to evaluate OMS721 in patients with complement-mediated TMAs was cleared by the FDA in April 2014. A Phase 2 clinical program is currently in progress. OMS721 has received Orphan Drug designation for the prevention (inhibition) of complement-mediated-TMAs.

In November 2014, we announced positive data using a Phase 2a derivative of OMS721 in a well-established animal model of stroke. Compared to control antibody-treated mice, mice treated with MASP-2 antibody in this study demonstrated significantly reduced neurological deficits 48 hours after an ischemic stroke. In addition, the infarcted area of the brain was significantly smaller in MASP-2 antibody-treated mice. A similar degree of protection was also observed in gene-targeted MASP-2-deficient mice, which showed significantly lesser neurological deficits and infarct sizes compared to wild-type control mice.

In October 2014, we announced the suspension of our Huntington's clinical trial for OMS824 resulting from an observation in a nonclinical study in rats being conducted concurrently with our Huntington's trial. Following preliminary data collection from that nonclinical study, we submitted a report on an observation in several of the rats receiving the maximum dose administered in the study to the FDA's Division of Neurology Products and its Division of Psychiatry Products, the FDA divisions which cleared our Investigational New Drug applications for Huntington's disease and schizophrenia, respectively. In response to a request from the FDA in follow-up communications, we suspended the ongoing Huntington's disease trial. The FDA has requested that we further evaluate the nonclinical data from the study in rats, as well as from nonclinical studies that we conducted that did not yield the observation, to characterize the observation more fully before we can reinitiate clinical enrollment in our OMS824 clinical program, including our Phase 2 Huntington's clinical trial or other clinical trials in our Huntington's or schizophrenia programs. 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. We also are seeking Fast Track designation for OMS824 for schizophrenia.

OMS103, a PharmacoSurgery product candidate, is being developed for use during arthroscopic procedures, including partial meniscectomy surgery. Our Phase 3 clinical program in arthroscopic partial meniscectomy surgery may be redesigned to include reduction of early postoperative pain as the primary endpoint. In addition, we are evaluating alternative approaches for making OMS103 commercially available, such as through a registered outsourcing facility without the need to conduct any additional clinical trials.

Development Programs

Our preclinical programs include: (1) our PDE7 program in which we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders, (2) our Plasmin program in which 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), (3) our proprietary ex vivo antibody platform and (4) our orphan GPCR platform in which we are working to complete high-throughput surrogate de-orphanization of orphan GPCRs, identifying small-molecule compounds that bind and functionally interact with the receptors and to develop product candidates that act at these new potential drug targets. To date, we have identified and confirmed sets of small-molecule compounds that interact selectively with, and modulate signaling of, each of 54 Class A orphan GPCRs, as well as two Class B GPCRs (glucagon-like peptide-1 receptor, or GLP-1R, and parathyroid hormone 1 receptor, or PTH-1R). We have initiated medicinal chemistry efforts to optimize compounds against several orphan GPCRs including GPR17, tied to re-myelination, GPR151, linked to neuropathic pain, and GPR161, which is strongly associated with triple negative breast cancer.

Financial Summary

The majority of our operating expenses to date have been for research and development activities. Research and development expenses consist of costs associated with research activities as well as costs associated with our product development efforts, which include clinical trial expenses and, prior to the point we receive approval in either the U.S. or the EU, third-party manufacturing services. Internal research and development costs are recognized as incurred.

Third-party research and development costs are expensed when the contracted work has been performed and when milestone payments are made. Research and development expenses include:

- employee and consultant-related expenses, which include salaries and benefits, and non-cash stock-compensation;

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- external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations prior to product approval, clinical research organizations, or CROs, clinical trial sites, and collaborators or licensors;
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and depreciation of leasehold improvements and equipment; and
- third-party supplier expenses including laboratory and other supplies.

We recognized net losses of $18.3 million and $13.9 million for the three months ended September 30, 2014 and 2013, respectively, and $53.0 million and $38.0 million for the nine months ended September 30, 2014 and 2013, respectively. These losses have resulted principally from expenses incurred in connection with research and development activities, consisting primarily of manufacturing services, clinical trials and preclinical studies associated with our current product and product candidates. Compared to 2013, we expect our 2014 net losses to increase as we continue to add personnel for our anticipated growth and to prepare for the U.S. commercial launch of Omidria planned for early 2015, to advance our clinical trials, and to expand our research and development efforts. As of September 30, 2014, our accumulated deficit was $307.3 million, total shareholders' deficit was $26.6 million and we had $21.8 million in cash, cash equivalents and short-term investments.

Results of Operations

In May 2014, the FDA approved Omidria for use during cataract surgery and we began calling on ophthalmic surgeons and their staff in the U.S. in August 2014. In October 2014 we were granted transitional pass-through reimbursement status from the CMS, which will become effective on January 1, 2015. We expect to begin selling Omidria in the U.S. in early 2015. With respect to the EU, an opinion on our MAA is expected before the end of the first quarter and we will begin marketing Omidria in the EU subsequent to approval and, most likely, entering into a partnership for European marketing and distribution. Due to the above and our lack of history of Omidria sales, we are not able to estimate future revenues from Omidria.

Revenue

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Small Business Innovative Research Grants	$214	$196	$359	$461
Vulcan Inc.	—	—	—	970
Total Revenue	$214	$196	$359	$1,431

Historically, our revenue has consisted of grant funding and revenue recognized in connection with funding from third parties. Other than these funding sources, we do not expect to receive product revenue until we begin selling Omidria in the U.S., which is currently expected in early 2015, and we do expect to receive revenue from our product candidates unless we receive regulatory approval and commercialize our product candidates or enter into collaborative agreements for the development and commercialization of our product and product candidates. We continue to pursue government and private grant funding as well as collaboration funding for our product candidates and research programs.

The increase in revenue during the three months ended September 30, 2014 compared to the prior year quarter was due to an increase in research activity on our NIH grant projects.

The decrease in revenue during the nine months ended September 30, 2014 compared to the prior year period was primarily due to lower revenue recognized from our GPCR program funding agreement with Vulcan Inc. and its affiliate, which we collectively refer to as Vulcan. We recognized the remaining deferred revenue in connection with the Vulcan agreement as revenue in the first quarter of 2013, and as of that date no further revenue remains to be recognized under the agreement. In addition, there was a decrease in revenue recognized from our NIH grants during the nine months ended September 30, 2014 due to a reduction of research activity on our NIH grant projects in the first half of the current year.

Research and Development Expenses

Our research and development expenses can be divided into 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. The following table illustrates our expenses associated with these activities:

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Direct external expenses:				
Clinical research and development:				
OMS824	$2,940	$2,104	$9,700	$4,423
OMS721	1,749	898	6,365	898
Omidria	1,479	1,099	3,933	3,414
Other clinical programs	70	14	113	400
Total clinical research and development	6,238	4,115	20,111	9,135
Preclinical research and development	413	470	1,402	4,081
Total direct external expenses	6,651	4,585	21,513	13,216
Internal, overhead and other expenses	4,242	3,464	11,892	10,377
Stock-based compensation expense	879	1,371	2,791	2,518
Total research and development expenses	$11,772	$9,420	$36,196	$26,111

The increase in total research and development expenses during the three months ended September 30, 2014 compared to the same period in 2013 was due primarily to higher manufacturing costs related to our Phase 2 clinical program evaluating OMS721 for the inhibition of complement-mediated TMAs, our Phase 2 clinical program evaluating OMS824 for the treatment of Huntington's disease and our Phase 1 trials evaluating the safety, tolerability and pharmacokinetics of OMS824 in healthy subjects. Additional increases in research and development expenses include costs related to Omidria, primarily expenses incurred for contract research. For the three months ended September 30, 2014, the non-cash stock compensation expense decreased compared to the same period in 2013 due to the grant of stock options during the third quarter of 2013 related to annual performance reviews. In October 2014, in connection with our annual employee review process, we granted qualified employees options to purchase approximately 1.2 million shares of our common stock with an exercise price of $11.58.

The increase in total research and development expenses during the nine months ended September 30, 2014 compared to the same period in the prior year was due primarily to higher manufacturing and clinical trial expenses related to our Phase 2 clinical trial evaluating OMS721 for the inhibition of complement-mediated TMAs and for our Phase 1 and Phase 2 clinical programs evaluating OMS824 for the treatment of schizophrenia and of Huntington's disease as well as higher clinical trial costs related to ongoing trials for Omidria. These increased expenses for the nine months ended September 30, 2014 compared to the same period in 2013 were partially offset by lower preclinical activity on our PDE7 program. We expect our research and development expenses to increase in the near term as we continue to advance our clinical product candidates through development, initiate or continue pediatric and other studies for Omidria, and initiate clinical trials for our Plasmin and PDE7 programs.

Direct external clinical research and development expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations, CROs, clinical trial sites, collaborators, licensors and consultants. Direct external preclinical research and development expenses consist primarily of third-party manufacturing organizations and CROs, laboratory supplies and consulting. 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. Our internal resources, employees and infrastructure are generally not directly tied to any individual research project and are deployed across multiple clinical and preclinical projects we are advancing in parallel.

At this time, 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, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates. Clinical development timelines, the probability of success and development costs can differ materially as expectations change. While we currently are focused on advancing our product development programs, our future research and development expenses will depend

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

The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals,

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could cause a delay in generating product revenue and cause our research and development expenses to increase 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 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,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Selling, general and administrative, excluding stock-based compensation expense	$4,788	$3,370	$11,904	$10,088
Stock-based compensation expense	786	840	2,292	1,846
Total selling, general and administrative expenses	$5,574	$4,210	$14,196	$11,934

The increase in selling, general and administrative expenses during the three and nine months ended September 30, 2014 was primarily due to sales and marketing costs related to our planned commercial launch of Omidria in the U.S. This increase was primarily due to costs related to hiring sales managers and our marketing team, contract costs for our field sales representatives, and an increase in marketing activities for Omidria in the 2014 period.

In June 2014, we entered into an agreement with Ventiv Commercial Services, LLC, or inVentiv, for field sales representatives and related sales support systems for the U.S. commercial launch of Omidria. As of September 30, 2014, we have a monthly fee of approximately $300,000. 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 any time subsequent to January 2016. In October, 2014, we amended the inVentiv agreement to add additional sales representatives in the U.S. Under the terms of the amendment, our total monthly fee will increase to approximately $630,000 upon inVentiv providing additional sales representatives, which is expected in January 2015, and will continue through January 2016.

Interest Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Interest expense	$944	$592	$2,555	$1,768

The increase in interest expense during the three and nine months ended September 30, 2014 was due to a higher average balance on our note payable during the 2014 period due to our entry in March 2014 into a new loan agreement, or the Oxford/MidCap Loan Agreement, with Oxford Finance LLC, or Oxford, and MidCap Financial SBIC, LP, or MidCap, under which we increased the aggregate amount of our outstanding indebtedness by approximately $12.7 million.

Other Income (Expense), Net

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Other income (expense), net	$(254)	$154	$(382)	$421

Other income (expense) principally includes rental income and non-cash charges associated with warrant modifications. The change in other income (expense) for the three months ended September 30, 2014 was due to a $411,000 charge related to extending the exercise period by six months of warrants to purchase up to 192,789 shares of our common stock in September 2014. The change in other income (expense) during the nine months ended September 30, 2014 is primarily due to $863,000 of charges related to extending the exercise period of warrants to

purchase 197,478 shares of our common stock by six months in March 2014 and extending the exercise period of warrants to purchase 192,789 shares of our common stock by an additional

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six months in September 2014. Rental income partially offsets the non-cash warrant charges in both the three and nine month periods in 2014 and was consistent with the same periods in the prior year.

Financial Condition - Liquidity and Capital Resources

As of September 30, 2014, we had $21.8 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.

In March 2014, we sold 3.5 million shares of our common stock in a public offering at a public offering price of $11.50 per share. After deducting offering expenses and underwriter discounts, we received net proceeds from the transaction of $37.8 million. Also in March 2014, we terminated our existing loan agreement with Oxford and entered into the Oxford/MidCap Loan Agreement, whereby we received $12.7 million in additional funds and deferred the repayment of principal under the new loan agreement until April 1, 2015.

The audit report covering our 2013 consolidated financial statements contained a “going concern” explanatory paragraph based on our losses and financial condition as of December 31, 2013. Subsequent to the March 13, 2014 issuance of the audit report, as stated above, we received net proceeds of $37.8 million from the sale of our common stock in the public offering and $12.7 million in incremental borrowings under the Oxford/MidCap Loan Agreement, both in March 2014. We believe that our existing cash, cash equivalents and short-term investments, together with anticipated future product sales of Omidria, and funds that we may be able to raise through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales, will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months. Corporate partnerships, public or private equity sales, additional debt financings, corporate collaboration and licensing arrangements or asset sales may not be available on terms that are acceptable to us, if at all, and any further equity financing would dilute the ownership of our existing shareholders. If we are unable to raise capital as and when needed, such failure would have a significant negative impact on our financial condition.

	Nine Months Ended September 30,	
	2014	2013
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	$(42,353)	$(29,399)
Investing activities	(8,325)	12,845
Financing activities	50,044	16,184

Operating Activities. Expenditures related to operating activities were primarily for research and development and selling, general and administrative expenses in support of our operations. Net cash used in operating activities increased for the nine months ended September 30, 2014, as compared to the same period in 2013 by $13.0 million, primarily due to higher operating expenses relating to preparing for the U.S. commercial launch of Omidria, manufacturing of material associated with the Phase 2 clinical trials evaluating OMS824 in Huntington’s disease, and clinical costs associated with the Phase 2 clinical trial evaluating OMS721 in complement-mediated TMAs, which led to an increase in our net loss of $15.0 million. This net loss was partially offset by a $1.7 million increase in non-cash charges, primarily related to increases in stock compensation and warrant modification expenses and $338,000 of cash provided due to the net change in operating assets and liabilities.

Investing Activities. Investing activities, other than the purchases of property and equipment, consist primarily of purchases and sales of short-term investments. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and receipts 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, 2014 was primarily due to the purchase of short-term investments with the proceeds we received from the sale of common stock in our public offering and borrowings under the Oxford/MidCap Loan Agreement, both of which occurred in March 2014, and is partially offset by the sale of short-term investments to provide cash for operating activities.

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Financing Activities. Net cash provided by financing activities in the nine months ended September 30, 2014 was due primarily to the $37.8 million of net proceeds that we received 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, both of which occurred in March 2014. During the 2013 period, cash provided by financing activities was primarily due to the $16.1 million we received in our registered direct offering in May 2013 in which we sold 3.9 million shares of common stock. During the period, from January 2014 to March 2014, we also paid $1.5 million of principal on the then outstanding Oxford notes. For the nine months ended September 30, 2013, no cash was used for principal payments on the Oxford notes as we amended the notes in December 2012 to provide for interest-only payments through December 31, 2013.

Funding Requirements

Because of the numerous risks and uncertainties associated with the development and commercialization of Omidria and our product candidates, and to the extent that we may or may not enter into collaborations with third parties to participate in the development and commercialization of Omidria or one or more of our product candidates, we are unable to estimate the amounts of increased capital requirements and operating expenditures required in the future. Our future operating and capital requirements will depend on many factors, including:

- the commercial success of Omidria in the U.S.;
- our ability to enter into a partnership for the distribution of Omidria in the EU;
- the commercial success of Omidria in the EU, if and when Omidria is approved for sale and we have entered into a partnership for the marketing and distribution of Omidria in the EU;
- the progress and results of our preclinical and clinical programs;
- the costs of commercialization activities, including product manufacturing, marketing, sales and distribution and related support activities;
- the cost, timing and outcomes of the regulatory processes for our product candidates;
- the extent to which we raise capital by selling our stock or entering into other forms of financing including debt agreements;
- the terms and timing of receipts or payments related to collaborative or licensing agreements we have or may establish;
- the hiring of new employees to support the commercialization of Omidria and the continued advancement of our development programs;
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to these types of transactions; and
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

We expect our continued operating losses to result in an increase in the total amount of cash used in operations until at least the time that Omidria becomes cash flow positive, which may be in several years, if at all. To meet our future capital requirements, we will need to fund our future cash needs through corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we do not raise additional capital through equity or debt financings or collaborations and licensing arrangements, we may be required to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts. We currently do not have any commitments for future external equity or debt funding.

Loan and Security Agreement

In March 2014, we entered into the Oxford/MidCap Loan Agreement with Oxford and MidCap, pursuant to which we borrowed $32.0 million. We used approximately $19.1 million of the loan proceeds to satisfy all of the amounts owed by us under our then-outstanding loan from Oxford and, after deducting all loan initiation costs including a $160,000 upfront loan initiation fee and lenders' legal costs, we received $12.7 million in net proceeds. Part of the costs paid included $520,000 for the prorated portion of the $1.4 million loan maturity fee payable under our then-outstanding loan agreement with Oxford, with no further obligation for the remaining $880,000. We have used, and intend to continue to use, the loan proceeds for general corporate purposes and working capital.

Interest on the amounts borrowed under the Oxford/MidCap Loan Agreement accrues at an annual fixed rate of 9.25%. Payments due under the Oxford/MidCap Loan Agreement are interest-only, payable monthly, in arrears, through March 1, 2015. Beginning April 1, 2015, 36 payments of principal and interest are payable monthly, in arrears. All unpaid principal and accrued and unpaid interest are due and payable on March 1, 2018.

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In consideration for the lenders agreeing to provide us with a one-year period of interest-only payments, we will be required to pay the lenders a final payment fee equal to 7.00% of the original principal amount borrowed under the Oxford/MidCap Loan Agreement (i.e., $2.2 million), less any portion of the fee previously paid in connection with a prepayment. We may prepay all or a portion of the outstanding principal and accrued and unpaid interest at any time upon prior notice to the lenders and the payment of a fee equal to 1.00% of the prepaid principal amount in addition to the pro rata portion of the final payment fee attributable to the prepaid principal amount. As security for our obligations 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 incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, pledge our intellectual property or repurchase stock. Additionally, the Oxford/MidCap Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breach, occurrence of a material adverse effect, or MAE (as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgment defaults and a change 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.

MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our inability to repay any portion of the loans in accordance with the terms of the Oxford/MidCap Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the enforceability of any material provision of the Oxford/MidCap Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce their rights and remedies under the Oxford/MidCap Loan Agreement or related agreements. We considered the MAE definition and believe that the MAE clause has not been triggered as of September 30, 2014.

Contractual Obligations and Commitments

The following table presents a summary of our contractual obligations and commitments as of September 30, 2014:

	Payments Due Within				
	1 Year	2-3 Years	4-5 Years	More than 5 Years	Total
	(In thousands)				
Operating leases	$3,902	$8,201	$8,555	$38,813	$59,471
Capital leases (principal and interest)	54	109	62	—	225
Notes payable (principal and interest)	7,608	24,512	6,128	—	38,248
Goods & services	4,269	1,268	—	—	5,537
Total	$15,833	$34,090	$14,745	$38,813	$103,481

Operating Leases

We currently 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, 2014, the remaining aggregate non-cancelable rent payable under the initial term of the lease was approximately $59.4 million.

Goods & Services

In June 2014, we entered into an agreement with Ventiv Commercial Services, LLC, or inVentiv, for field sales representatives and related sales support systems for the U.S. commercial launch of Omidria. As of September 30, 2014, we had a monthly fee of approximately $300,000. 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 any time subsequent to January 2016. The estimated costs for this agreement through January 2016 are included in the table above.

In October, 2014, we entered into an amendment to the agreement with inVentiv to add additional sales representatives in the U.S. Under the terms of the amendment, our total monthly fee will increase to approximately $630,000 upon inVentiv providing additional sales representatives, which is expected in January 2015, and will continue through January 2016. The estimated costs for this amendment are not included in the table above as the agreement was entered into in October 2014.

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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 as of September 30, 2014 is included in the table above.

In October 2014, we entered into a non-exclusive agreement with Hospira S.p.A and Hospira Worldwide, Inc. (together, "Hospira") for commercial supply of Omidria. The agreement has an initial term of five years from the date of first commercial sale of Omidria. In connection with the commencement of commercial processing of Omidria at Hospira, we are obligated to provide Hospira with monthly rolling forecasts that will be used to calculate our firm commitment. We have not commenced commercial manufacturing of Omidria at Hospira and, therefore, do not currently have any firm purchase commitments under this agreement.

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 the events triggering the commencement of payment obligations will occur. See Note 8 to our consolidated financial statements in our 2013 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 13, 2014 for a description of the agreements that include these royalty and milestone payment obligations.

Critical Accounting Policies and Significant Judgments and Estimates

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S. The preparation of our financial statements 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.

In relation to our commercial launch of Omidria, capitalization of costs as inventory will begin on lots manufactured after the regulatory approval date for Omidria, which was May 30, 2014 in the U.S. Inventory is stated at the lower of cost or market. We expense inventory costs related to product candidates as research and development expenses prior to regulatory approval in the respective territory.

For a more detailed listing of our other critical accounting estimates, refer to our 2013 Annual Report on Form 10-K filed with the SEC on March 13, 2014.

Off-Balance Sheet Arrangements

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

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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, 2014, we had cash, cash equivalents and short-term investments of $21.8 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 materially 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 do not believe that we are 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, 2014. 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, 2014, 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.

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PART II—OTHER INFORMATION

ITEM 1A. RISK FACTORS

Our business, prospects, financial condition or operating results could be materially adversely affected by any of the risks and uncertainties described below, as well as other risks not currently known to us or that we currently deem immaterial. You should carefully consider these risks before making an investment decision. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2013.

Risks Related to Our Products, Programs and Operations

We are focusing a significant portion of our activities and resources on Omidria, and if we are unable to commercialize Omidria successfully, our inability to generate significant revenue from the sales of Omidria would adversely impact our ability to achieve profitability.

We are a biopharmaceutical company with one product approved by the FDA for commercial sale in the U.S., Omidria™ (phenylephrine and ketorolac injection) 1%/0.3% for use during cataract surgery or ILR. Omidria was approved by the FDA on May 30, 2014 and we anticipate beginning commercial sales of Omidria in early 2015. Consequently, we have not yet generated any revenue from any product sales to date. We may not be able to commercialize Omidria successfully for a number of reasons, including:

- a lack of acceptance of Omidria by physicians, patients, third-party payors 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 limited number of manufacturers of Omidria and a limited number of suppliers of the product's active pharmaceutical ingredients, excipients and packaging materials;
- reimbursement and coverage policies of government and private payors such as Medicare, Medicaid, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- the relative price of Omidria as compared to alternative options for maintenance of pupil size and reduction of postoperative ocular pain during cataract surgery or ILR;
- 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 Omidria successfully.

If we are not able to commercialize Omidria successfully 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 extent to which coverage and reimbursement for Omidria is available from government and private third-party payors such as Medicare, Medicaid, insurance companies, group purchasing organizations, health maintenance organizations and other plan administrators;
- the duration of transitional pass-through reimbursement status from CMS for Omidria and the continued availability of separate reimbursement once transitional pass-through reimbursement expires;
- the timing, cost and level of investment in our sales and marketing efforts to support Omidria sales;
- 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.

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In addition, from time to time, we may enter into collaboration agreements with other companies that may include commercial arrangements, development funding and/or significant upfront and milestone payments. Amounts earned from our collaboration agreements, if any, may be an important source of our revenues. Accordingly, our revenues may also depend on commercial arrangements, development funding and the achievement of development and clinical milestones under collaboration and license agreements. These upfront and milestone payments 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.

For these and other reasons, it is difficult for us to forecast accurately future profits or losses. As a result, it is possible that in some quarters our sales of Omidria and/or our operating results may not meet the expectations of securities analysts or investors, which could cause the trading price of our common stock to decline, perhaps substantially.

We cannot be certain that we will successfully commercialize any of our product candidates, even if we receive regulatory approval for our product candidates.

We have invested a significant portion of time and financial resources in the development of our product candidates, in addition to the development and commercialization of Omidria. Our ability to generate revenues depends on the commercial success of our product candidates that may be approved, as well as Omidria, which in turn will depend on several factors, including our ability to:

- generate commercial sales through our own sales force or contract sales organizations, or collaborations with pharmaceutical companies, that we may establish;
- establish effective marketing programs and build brand identity;
- obtain acceptance of our product candidates, if approved, by physicians, patients and third-party payors and obtain and maintain distribution of our products;
- establish and maintain agreements with distributors on commercially reasonable terms; and
- demonstrate commercial manufacturing capabilities, and maintain commercial manufacturing arrangements with third-party manufacturers, necessary to meet the commercial demand for a product.

If we fail to commercialize successfully product candidates in our pipeline, if approved, or if we are significantly delayed in doing so, we may be unable to generate sufficient revenues to grow our business, which would materially and adversely affect our business, financial condition and results of operations.

Omidria and our product candidates, if commercialized, may never achieve market acceptance.

The commercial success of Omidria and our product candidates, if commercialized, will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community. If Omidria or our product candidates, if commercialized, fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, Omidria or any product candidate that we may develop and commercialize will depend on many factors, including:

- our ability to provide acceptable evidence of safety, efficacy and product quality;
- the availability and relative cost and efficacy of alternative and competing treatments;
- the effectiveness of our marketing and distribution strategy to, among others, hospitals, surgery centers, physicians and/or pharmacists;
- the prevalence of the condition for which the product is approved or commercialized or frequency of the related surgical procedure;
- the acceptance by physicians of each product as a safe and effective treatment;
- the perceived advantages over alternative treatments;
- the relative convenience and ease of administration;
- the availability of adequate reimbursement by Medicare and other third parties;
- the frequency and severity of adverse side effects; and
- publicity concerning our products or competing products and treatments.

Further, the number of procedures in which Omidria or any of our PharmacoSurgery product candidates, if commercialized, would be used may be significantly less than the total number of such procedures performed. If

Omidria or our product candidates, if commercialized, do not receive sufficient levels of acceptance from physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable. If we are unable to gain or increase market penetration with Omidria or our product candidates, if commercialized, our growth prospects would be significantly harmed.

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

Our future revenue and profit will depend heavily on the pricing and availability of adequate reimbursement for the use of our approved products, including Omidria, from governmental and other third-party payors, both in the U.S. and in other countries. Even if we are successful in bringing one or more products to market, these products may not be considered cost-effective, and the amount reimbursed for any product may be insufficient to allow us to sell the product profitably. Reimbursement by a third-party payor may depend on a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for any product from each government or third-party payor 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 payor. We can provide no assurances at this time regarding the cost-effectiveness of Omidria 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, or product candidates 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.

There may be significant delays in obtaining reimbursement coverage for newly approved products, and we may not be able to provide data sufficient be granted reimbursement. Even when a payor 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 foreign regulatory agencies and/or appear in a recognized drug compendium, and other conditions may apply. Increasingly, third-party payors who reimburse healthcare costs, such as government and private payors, are requiring that companies provide them with predetermined discounts from list prices and challenging the prices charged for medical products. 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. 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 usually granted for a limited duration and we expect pass-through reimbursement status for Omidria to last for two to three years from the January 1, 2015 effective date.

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.

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 or is significantly delayed, our business could be materially harmed.

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

Omeros has never sold, marketed or distributed any biopharmaceutical product. Developing a sales force for any product is expensive and time-consuming, and a delay in hiring and training a sales force, or difficulties managing a contract sales force, could impact the timing or effectiveness of any product launch. We have entered into an agreement with inVentiv for a field sales force and related sales operation services for the U.S. commercial launch of Omidria but we have never operated or managed an internal or third-party sales force for any approved product.

Factors that may inhibit our efforts to commercialize any approved products, including Omidria, without commercialization partners include:

- our inability to recruit in a timely manner, and retain, adequate numbers of effective sales and marketing personnel, or to partner or contract with a third party to provide sales and marketing services, in the applicable region of the world;
- the inability of sales personnel to sell or promote any approved product(s) to adequate numbers of hospitals, surgery centers, physicians and/or pharmacists;

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- our inability to develop and maintain, or access, adequate information systems to monitor sales by distribution channel, report pricing, maintain customer lists and track selling and marketing operations;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating a sales and marketing organization.

If we are unsuccessful in building and managing a sales and marketing infrastructure internally or through a third-party partner for any approved product, we will have difficulty commercializing the product, which would adversely affect our business and financial condition.

In the EU, we plan to enter into partnerships for Omidria marketing and distribution 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 obtain approvals from 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 are subject to extensive government regulation, including the regulations associated with approval for marketing of Omidria and our product candidates.

Both before and after approval of any product, we, Omidria and our product candidates, 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, among other things, 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 being exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials.

Omidria is our only product approved by the FDA, and the FDA has not approved any of our product candidates for sale in the U.S. Obtaining FDA approval requires substantial time, effort, and financial resources, and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on 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. For example, we have had to suspend clinical trials of OMS824 based on a nonclinical finding, and the FDA has required that we review and further evaluate our nonclinical data before the FDA may permit us to resume or initiate further clinical trials in our OMS824 Huntington's and schizophrenia clinical programs. If, based on our review and evaluation of these data, the FDA concludes that there is an unwarranted safety risk to patients, the FDA may require us to run additional nonclinical studies before permitting us to resume or initiate additional clinical trials, may impose limits on such trials or may not permit us to resume or initiate clinical trials at all. As we develop our product candidates, we periodically discuss with the FDA clinical, regulatory and manufacturing matters, and our views may, at times, differ from those of the FDA. For example, the FDA regulates Omidria and our product candidates that consist of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's claimed effect. The FDA has maintained questions regarding whether available data and information provided to the FDA demonstrate the contribution of each active ingredient in OMS103. If we are unable to resolve these or any other questions by the FDA, we may be required to provide additional information, which may include the results of additional preclinical studies or clinical trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond 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, such as Omidria in the U.S., such approval may be subject to significant limitations on the indicated uses for which that product may be marketed, conditions of use, and/or significant

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post approval obligations, including additional post-marketing studies and clinical trials. These regulatory requirements may, among other things, limit the size of the market for the approved product. Even after approval, discovery of previously unknown problems with an approved product, manufacturer, or facility, such as previously undiscovered side effects or adverse effects, may result in restrictions on any product, manufacturer, or facility, including, among other things, a possible withdrawal of approval of the approved product. The realization of any of these risks could harm our business and operating results.

The 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 requirements requires the expenditure of substantial resources and attention, and the failure to comply with these requirements could result in substantial fines or penalties.

In the United States, the commercialization of Omidria and our product candidates, if approved, is subject to regulation and enforcement under a number of federal and state health-care compliance laws. For example, the FDA requires that we advertise and promote our approved products only for uses that FDA has approved and for which we provide appropriate information about safety risks to balance information presented about product effectiveness. The federal Anti-Kickback Law prohibits offering or paying anything of value to a person or entity to induce the use of a good or service covered by a federal health care program such as Medicare or Medicaid. The federal False Claims Act prohibits presenting or causing to be presented a false claim for payment by a federal health care program, and this law has been interpreted to include claims caused by improper drug-manufacturer product promotion or the payment of kickbacks. We are subject to a variety of governmental pricing, price reporting, and rebate requirements, including those under Medicaid and the Veterans Health Care Act. Under the so-called Sunshine Act and related provisions of the Affordable Care Act, we must report to the federal government information on financial payments we make to physicians and certain health care institutions and also on drug samples that we distribute. In addition to these federal law requirements, there are related state law requirements. Also, if we receive protected patient health information, we may be subject to federal or state privacy laws.

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

In order to comply with these United States and other laws, we must establish and maintain an effective healthcare compliance program. This requires the expenditure of significant time and resources. If we are found to be in violation of any of these laws, there could be considerable civil or criminal penalties. 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.

We have a history of operating losses, and we may not achieve or maintain profitability.

We have not been profitable and have generated substantial operating losses since we were incorporated in June 1994. As of September 30, 2014, we had an accumulated deficit of approximately $307.3 million. We do not anticipate generating revenue from the sale of our first FDA-approved product, Omidria, until 2015 at the earliest and may incur additional losses depending upon the commercial success of Omidria, and we cannot be certain that we will ever achieve profitability. We will continue to incur significant and increasing costs as we support the commercial launch of Omidria in the U.S. and, if approved, in the EU and other foreign territories, as well as incurring costs associated with conducting additional research on our product candidates. As a result, our business is subject to all of the risks inherent in the development of a new business enterprise, such as the risks that we may be unable to obtain the additional capital needed to support the preclinical and clinical development and commercialization of any of our product candidates should they be approved, to develop a market for Omidria and our product candidates, if approved, to successfully transition from a company with a research and development focus to a company capable of commercializing products, and to attract and retain qualified management as well as technical and scientific staff.

If we are unable to raise additional capital when needed, we may be unable to complete the development and commercialization of Omidria and our product candidates or to continue our other preclinical development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- continue the commercialization of Omidria;
- continue the clinical development of OMS824 and OMS721;
- continue the development of OMS103 for use in arthroscopic partial meniscectomy surgery;

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- continue our development efforts in our GPCR program to advance this program for potential partnering and/or for internal development of product candidates targeting GPCRs;
- scale-up and produce clinical and commercial supplies of Omidria and our product candidates, and conduct clinical studies for Omidria and our product candidates, including OMS103, OMS824, OMS721, and product candidates being developed in our PDE7 and Plasmin programs;
- continue research and development in all of our programs;
- make principal and interest payments when due under the Oxford/MidCap Loan Agreement;
- initiate and conduct clinical trials for other product candidates;
- make milestone payments to our collaborators;
- undertake development activities and make the required payments to maintain our exclusive licenses to our MASP-2 program; and
- launch and commercialize any product candidates for which we receive regulatory approval.

If we do not raise additional capital through one or more funding avenues (e.g., corporate partnering, debt, equity financings, etc.), we may be unable to commercialize Omidria or complete all of the clinical trials in our Phase 3 clinical program for OMS103, which could prevent us from generating sales revenue for Omidria and/or OMS103, respectively. Furthermore, we may need to raise additional capital to continue the clinical development of OMS824, OMS721 and our other clinical programs and to advance one or more of our preclinical programs into clinical development. Also, our clinical trials may be delayed or we may need to conduct additional trials for many of the reasons discussed in these “Risk Factors,” which would increase our development expenses and may require us to raise additional capital to commercialize Omidria and complete the clinical development and commercialization of our product candidates and to decrease spending on our other development programs. If we are unable to raise sufficient capital to commercialize Omidria, complete the clinical development of OMS721 and/or OMS824, or advance the development of one or more of our other programs, our business and prospects could be harmed and our stock price could decline significantly.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing Omidria or our product candidates internationally.

We intend to have Omidria and our product candidates, if approved, marketed outside the U.S. In order to market Omidria or any of our product candidates, if approved, in the EU and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Although we have filed for regulatory approval of Omidria in the EU, we may be unable to file for regulatory approvals in other non-U.S. geographies and may not receive necessary approvals to commercialize Omidria or any of our product candidates in any non-U.S. market. 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 EMA 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 or EMA. The failure to obtain regulatory approval in one or more foreign jurisdictions for Omidria or any of our product candidates could harm our business.

We have submitted an MAA with the EMA for Omidria, which is currently under review. The EU regulatory process is subject to substantial agency discretion and risks, including those described elsewhere in these “Risk Factors.” The EMA may decide not to approve our application, or to require us to obtain additional data regarding Omidria and to resubmit our marketing application(s) in order to consider Omidria for approval, further delaying our ability to market and generate revenue from the sale of Omidria in the EU. If there are any negative decisions or delays in the regulatory process, the market price of our common stock could decline significantly.

We cannot be certain that OMS103 will receive regulatory approval.

Our Phase 3 clinical program evaluating OMS103 in patients undergoing arthroscopic partial meniscectomy may be redesigned to include postoperative pain reduction as the primary endpoint before further clinical studies are conducted, if we elect to conduct additional OMS103 trials. While OMS103 demonstrated a drug effect in the first Phase 3 clinical trial by reducing early postoperative pain, which was a secondary endpoint, we can provide no assurance that in subsequent trials, OMS103 will meet the primary endpoint of early postoperative pain reduction or that the design of our Phase 3 program will be acceptable to regulatory authorities. Also, we can provide no assurances that we will have sufficient resources to conduct any subsequent clinical trials that we or regulatory authorities may deem necessary, including any trial regulatory authorities require

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to show a contribution from each drug in the OMS103 combination. If the data from any subsequent trials are negative or if our program design, data analysis, and proposed label claims are not acceptable to regulatory authorities, we may be unable to seek, or be significantly delayed in seeking, marketing approval of OMS103, which could cause the market price of our common stock to decline significantly.

We may find it difficult to prevent compounders from preparing compounded formulations of Omidria or our product candidates that may compete with Omidria or our product candidates, if and when commercialized.

In November 2013, President Obama signed the Drug Quality and Security Act, which provided for the oversight of compounded human drugs. The law permits a compounding pharmacy to voluntarily register with the FDA as an outsourcing facility and create compounded products, subject to certain requirements including compliance with good manufacturing practices, or GMPs, for outsourcing facilities and FDA inspection. Registered outsourcing facilities will be permitted to compound products in large quantities instead of pursuant to individual patient prescriptions. Outsourcing facilities may not engage in wholesale selling of compounded drugs, compound a drug that is essentially a copy of a commercially available drug, or compound drugs that the FDA identifies as prohibited for compounding. Outsourcing facilities will still be subject to potential liability for patent infringement by compounding patented drugs. It is not clear how many compounding pharmacies will register with the FDA as outsourcing facilities or how aggressively the FDA will implement the new law. It is also not clear to what extent traditional compounding pharmacies that do not register as outsourcing facilities will continue to produce compounded drugs without individual patient prescriptions. We may be unable to prevent a registered outsourcing facility or traditional compounding pharmacy from preparing a compounded formulation in large quantities that is similar to Omidria or OMS103 but outside the scope of the claims of our issued patents, or we may be unsuccessful in enforcing our issued patents against outsourcing facilities or traditional compounding pharmacies that prepare compounded formulations that are within the scope of our issued patents. Because these patent violations may be sporadic and dispersed, we may not easily be able to identify the violations. Such actions may hinder our ability to generate enough revenue to achieve profitability and adversely affect our margins.

We have no internal capacity to manufacture clinical or commercial supplies of Omidria or our product candidates and intend to rely solely on third parties to manufacture clinical and commercial supplies of Omidria and our product candidates.

We intend to rely on third party manufactures to produce commercial quantities of Omidria and any of our product candidates should they receive regulatory approval. Additionally, we intend to rely on third parties to produce clinical drug supplies need for clinical trials. With the exception of our agreements with Patheon and Hospira for the commercial supply of Omidria, and Hospira for the commercial supply of liquid OMS103, we have not yet entered into any agreement for the commercial supply of any of our other product candidates, and can provide no assurance that we will be able to do so on commercially reasonable terms, if at all. Our agreement with Patheon for the commercial supply of Omidria has a term extending through December 31, 2015, which term could be terminated early by either party upon the occurrence of certain specified events, including any mandate from a regulatory authority prohibiting manufacture at Patheon's relevant facility in the absence of an agreement with Patheon to transfer the manufacture of Omidria to an alternative Patheon facility. If the Patheon agreement is terminated before we have completed manufacturing method transfer, validation and approval of Hospira as a manufacturing site for Omidria or an alternative Patheon facility as a manufacturing site for Omidria, we could have a shortage of supply of Omidria. Even if Hospira has been established as a manufacturing site for Omidria, if we elect not to transfer manufacturing of Omidria from the current Patheon facility to an alternative Patheon facility, or if Patheon is unable or unwilling to manufacture Omidria at Patheon's planned alternative facility, or if our supply agreement with Patheon is terminated, we will have only Hospira as a source of supply of Omidria, which may be inadequate to meet product demand. The cost of transferring the Omidria manufacturing process to Hospira and potentially also to an alternate Patheon manufacturing facility or a different manufacturer, or any significant delays in the timely completion of these transfers of the Omidria manufacturing process, could materially harm our business and prospects. Any significant delays in the manufacture of clinical or commercial supplies of Omidria or our product candidates 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 and our product candidates and generate revenue may be significantly delayed.

Contract manufacturers that we select to manufacture Omidria or our product candidates for clinical testing or for commercial supply 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 Omidria and our product candidates. Once a product is approved and being 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. Even if we are able to establish additional or replacement manufacturers, identifying these sources and entering into

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definitive supply agreements and obtaining regulatory approvals may require a substantial amount of time and cost and such supply arrangements may not be available on commercially reasonable terms, if at all.

In addition, we and our contract manufacturers must comply with current good manufacturing practices, or GMPs, 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 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 to patients in our clinical trials or on a commercial scale 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. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must first approve these manufacturers' facilities and processes, which could require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of the applicable product(s).

Ingredients, excipients and other materials necessary to manufacture Omidria or our PharmacoSurgery product candidates may not be available on commercially reasonable terms, if at all, which may adversely affect the development and commercialization of Omidria or those PharmacoSurgery 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, for commercial distribution. Suppliers may not sell these ingredients, excipients or materials at the time they are needed or on commercially reasonable terms, if at all. 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. 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 these active pharmaceutical ingredients, excipients and materials as 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, significantly impacting our ability to develop and commercialize our product candidates, 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 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;

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- delays in enrolling patients into clinical trials;
- lower than anticipated retention rates of patients in clinical trials;
- the need to repeat or conduct additional clinical trials as a result of problems such as inconclusive or negative results, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol or an unacceptable study design;
- an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval;
- an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation;
- the occurrence of 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;
- 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.

For example, our Phase 2 clinical trial of OMS824 in Huntington's disease has been suspended. As a result, we may need to perform additional studies, the reinitiation of a Phase 2 clinical trial may be delayed or not allowed, or the trial's scope may be narrowed. Our OMS824 schizophrenia program may also be delayed or not allowed to initiate further clinical trials due to the current enrollment suspension in the OMS824 program.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards 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 Omidria or our product candidates 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;
- the availability of competing therapies and clinical trials;
- 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

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- 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. For example, we intend to use proprietary active ingredients that we have exclusively licensed from Daiichi Sankyo Co., Ltd. for our PDE7 program. 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 agreements with 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

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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 may not be successful in partnering new drug targets made accessible by our GPCR program.

To fully exploit the developments arising from our GPCR program, we intend to partner or out-license our proprietary rights associated with some of the new drug targets made accessible by our GPCR program. There can be no assurance that we will enter into any such agreements and, even if we do, that the terms of any such agreements will be favorable to us. For example, potential partners may require that we first advance the development and optimization of functionally active compounds identified from our high-throughput screening of orphan GPCRs prior to entering into a licensing or other partnering arrangement, requiring us to invest substantial resources without any certainty that we will successfully optimize one or more of the compounds or recover our investment. Potential partners may also require that we obtain the issuance of patents protecting the new drug targets and compounds that interact with those targets. We may not be successful in obtaining the issuance of such patents for the targets and compounds we intend to partner or for the targets and compounds we intend to develop ourselves and, even if we do, the breadth of our patent rights may be inadequate or may be viewed as inadequate by potential partners. Further, if we are unable to secure the issuance of patents or patents of adequate breadth, we may be unable to exclude competitors from developing and commercializing compounds that interact with GPCR targets, limiting our ability to successfully commercialize these targets either independently or with a partner.

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

Our MASP-2 program is based in part on intellectual property rights that we licensed on a worldwide exclusive basis from the University of Leicester, the UK Medical Research Council at Oxford University and 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 pay Helion up to $6.6 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 product candidates 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 and Plasmin programs depends on third-party developers and manufacturers of biologic drug products.

Any product candidate from our MASP-2 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 a manufacturer, which may increase our development costs, slow down our product development and approval process, delay receipt of product revenue and make it difficult to raise additional capital.

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.

Any product candidates from our preclinical programs, including our PDE7, Plasmin and GPCR programs, must successfully complete preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before entering clinical trials. Many pharmaceutical and biological 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

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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 development programs and are considering a variety of product candidates, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we must focus on clinical and preclinical development programs and product candidates 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, including our GPCR program, 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 assure you 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;

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- 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 advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

If we choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. 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 may not be able to do this. Proving

invalidity, in particular, is difficult since it requires clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Although we have conducted searches of third-party patents with respect to our 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

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cannot assure you 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.

Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents, our licensors' patents, our pending applications or our licensors' pending applications, or that we or our licensors were the first to invent or the first to file patent applications for inventions embodied in our technologies. Our competitors may have filed, and may in the future file, patent applications covering technologies similar to ours. Any such patent application may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If our or our licensors' pending patent applications issue as patents, we can provide you no assurances that the patents will not be challenged in post-grant review or inter-parties review proceedings. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in interference derivation proceedings declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Similar patent opposition proceedings in other countries and regions may also be costly and could result in the loss of patent rights in those countries and regions.

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.

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

In March 2014, we borrowed $32.0 million pursuant to the terms of the Oxford/MidCap Loan 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, so long as we owe any amounts to the lenders under the Oxford/MidCap Loan Agreement. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. In addition, if we default under 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.

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.

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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 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 more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage than 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. Section 404 requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting for each fiscal year. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses.

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.

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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, other pharmaceutical companies, many with significantly greater resources than we have, are developing PDE10 inhibitors similar to 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. For example, in 2012, Pfizer Inc. announced that its PDE10 inhibitor product candidate failed to demonstrate efficacy in a Phase 2 clinical trial evaluating the compound in acute exacerbation of schizophrenia. This and other potential clinical trial failures of PDE10 inhibitor product candidates may negatively reflect on the ability of OMS824 to demonstrate safety and efficacy. 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.

Any product candidate for which we obtain marketing approval, such as Omidria, 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;

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- 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 and maintain such insurance on acceptable terms or that we will be able to secure 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, 2014, our stock traded as high as $18.80 per share and as low as $6.92 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;
- EMA actions related to our MAA submission for Omidria;
- FDA or foreign regulatory actions related to Omidria or any of our product candidates, including the suspension by the FDA of our OMS824 Phase 2 clinical trial in Huntington's disease;
- results from our clinical development programs, including the data from our ongoing clinical development programs evaluating Omidria, OMS103, OMS824, OMS721 and PPAR ;
- announcements regarding the progress of our preclinical programs, including without limitation our GPCR program;
- quarterly variations in our results of operations or 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;
- any major change in our board or management;
- general economic conditions and slow or negative growth of our markets; and
- political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various 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

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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 Omidria and 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 9.3 million shares of common stock that are either subject to outstanding warrants or subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Anti-takeover provisions in our charter documents and under Washington law could make an acquisition of us, which may be beneficial to our shareholders, 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 acquirors to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it 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

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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.

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ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Unregistered Sales of Equity Securities. We issued 3,305 shares of our common stock upon the exercise of warrants to purchase 4,689 shares of our common stock in September 2014. We received proceeds of $37,828 from the cash exercise of 3,088 warrants upon payment of the cash exercise price of $12.25 per warrant. We also issued 217 shares of our common stock upon the cashless net exercise of 1,601 warrants. The warrants were issued on March 29, 2007 in connection with our Series E preferred stock financing in a transaction that was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. We deemed the issuance of common stock upon the exercise of these warrants to be exempt from registration under the Securities Act under the same provisions. No underwriters were involved in the issuance of our common stock upon the exercise of warrants and no commissions were paid in connection with such issuances.

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ITEM 6. EXHIBITS

Exhibit Number	Description
4.1*	Notice Regarding the Extension of the Expiration Date to March 29, 2015 of Warrants to Purchase up to an Aggregate of 192,789 Shares of Common Stock of the Registrant
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

* Incorporated by reference from the registrant's Current Report on Form 8-K filed on September 29, 2014 (File No. 001-34475).

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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 10, 2014	/s/ Gregory A. Demopulos Gregory A. Demopulos, M.D. President, Chief Executive Officer and Chairman of the Board of Directors
Dated: November 10, 2014	/s/ Michael A. Jacobsen Michael A. Jacobsen Vice President, Finance, Chief Accounting Officer and Treasurer