

OMEROS CORP  
Form 10-Q  
May 11, 2015  
Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-34475

OMEROS CORPORATION

(Exact name of registrant as specified in its charter)

Washington  
(State or other jurisdiction of  
incorporation or organization)

91-1663741  
(I.R.S. Employer  
Identification Number)

201 Elliott Avenue West  
Seattle, Washington  
(Address of principal executive offices)  
(206) 676-5000

98119  
(Zip Code)

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>

(Do not check if a smaller reporting company)

Edgar Filing: OMEROS CORP - Form 10-Q

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

As of May 7, 2015, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 37,832,261.

---



realized, they may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements, which represent our estimates and assumptions only as of the date of the filing of this

---

Table of Contents

Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable law, including the securities laws of the United States and the rules and regulations of the SEC, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

---

Table of Contents

OMEROS CORPORATION  
FORM 10-Q FOR THE QUARTER ENDED March 31, 2015  
INDEX

	Page
<u>Part I — Financial Information</u>	<u>3</u>
<u>Item 1. Financial Statements</u>	<u>3</u>
<u>Condensed Consolidated Balance Sheets as of March 31, 2015 (unaudited) and December 31, 2014</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2015 and 2014 (unaudited)</u>	<u>4</u>
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2015 and 2014 (unaudited)</u>	<u>5</u>
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>6</u>
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>12</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>19</u>
<u>Item 4. Controls and Procedures</u>	<u>19</u>
<u>Part II — Other Information</u>	<u>20</u>
<u>Item 1A. Risk Factors</u>	<u>20</u>
<u>Item 2. Unregistered Sales of Equity Securities</u>	<u>37</u>
<u>Item 6. Exhibits</u>	<u>38</u>
<u>Signatures</u>	<u>39</u>

---

Table of Contents

## PART I—FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## OMEROS CORPORATION

## CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(unaudited)

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$1,441	\$ 354
Short-term investments	68,621	6,532
Receivables	538	392
Inventory	566	568
Prepaid expense	1,784	1,191
Other current assets	116	120
Total current assets	73,066	9,157
Property and equipment, net	727	782
Restricted cash	679	679
Other assets	439	472
Total assets	\$74,911	\$ 11,090
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$4,611	\$ 4,915
Accrued expenses	6,438	7,070
Current portion of notes payable, net of discount	9,019	6,446
Total current liabilities	20,068	18,431
Notes payable, net of current portion and discount	23,906	26,263
Deferred rent	9,091	9,050
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Preferred stock, par value \$0.01 per share, 20,000,000 authorized; none issued and outstanding at March 31, 2015 and December 31, 2014	—	—
Common stock, par value \$0.01 per share, 150,000,000 authorized; 37,825,261 and 34,185,464 issued and outstanding at March 31, 2015 and December 31, 2014, respectively	378	342
Additional paid-in capital	368,183	285,050
Accumulated deficit	(346,715 )	(328,046 )
Total shareholders' equity (deficit)	21,846	(42,654 )
Total liabilities and shareholders' equity (deficit)	\$74,911	\$ 11,090
See notes to consolidated financial statements		

Table of Contents

## OMEROS CORPORATION

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended March 31,	
	2015	2014
Revenues		
Product sales	\$238	\$—
Grant revenue	150	100
Total revenue	388	100
Costs and expenses:		
Cost of product sales	11	—
Research and development	9,318	12,017
Selling, general and administrative	8,989	3,767
Total costs and expenses	18,318	15,784
Loss from operations	(17,930 )	(15,684 )
Interest expense	(957 )	(672 )
Investment income and other income (expense), net	218	(286 )
Net loss	\$(18,669 )	\$(16,642 )
Comprehensive loss	\$(18,669 )	\$(16,642 )
Basic and diluted net loss per share	\$(0.51 )	\$(0.54 )
Weighted-average shares used to compute basic and diluted net loss per share	36,483,559	30,897,039
See notes to consolidated financial statements		



Table of Contents

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

	Three Months Ended March 31,	
	2015	2014
Operating activities:		
Net loss	\$(18,669 )	\$(16,642 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of assets	—	(9 )
Depreciation and amortization	55	82
Stock-based compensation expense	2,517	1,788
Non-cash interest expense	212	136
Warrant modification expense	—	452
Changes in operating assets and liabilities:		
Receivables	(146 )	(109 )
Prepaid expenses and other current and noncurrent assets	499	(1,060 )
Accounts payable, accrued expenses and other	(1,944 )	4,223
Net cash used in operating activities	(17,476 )	(11,139 )
Investing activities:		
Purchases of property and equipment, net	—	(6 )
Purchases of investments	(79,389 )	(58,839 )
Proceeds from the sale and maturities of investments	17,300	19,934
Net cash used in investing activities	(62,089 )	(38,911 )
Financing activities:		
Proceeds from issuance of common stock and pre-funded warrants, net of offering costs	79,076	37,749
Net proceeds from borrowings under notes payable	—	12,699
Payments on notes payable	—	(1,464 )
Proceeds upon exercise of stock options and warrants	1,576	249
Net cash provided by financing activities	80,652	49,233
Net increase (decrease) in cash and cash equivalents	1,087	(817 )
Cash and cash equivalents at beginning of period	354	1,384
Cash and cash equivalents at end of period	\$1,441	\$567
Supplemental cash flow information		
Cash paid for interest	\$745	\$691
See notes to consolidated financial statements		

Table of Contents

OMEROS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a biopharmaceutical company committed to discovering, developing and commercializing both small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Our first drug product Omidria has been approved by the U.S. Food and Drug Administration (FDA) for use during cataract surgery or intraocular lens (IOL) replacement. We commenced a controlled launch of Omidria to a small number of ambulatory surgery centers (or ASCs) in the U.S. in February 2015. During the controlled launch, our sales were made on a direct, non-return basis and the majority of the patients were covered under Medicare Part B. In early April 2015, we initiated the broad U.S. launch of Omidria and we have begun to sell the product to wholesalers who will, in turn, sell to ASCs and hospitals.

Basis of Presentation

Our condensed consolidated financial statements include the financial position and results of operations of Omeros Corporation and our wholly owned subsidiaries. All inter-company transactions have been eliminated. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of March 31, 2015 and for the three months ended March 31, 2015 and 2014 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2014 has been derived from audited financial statements but does not include all of the information and footnotes required by GAAP. The accompanying unaudited condensed consolidated financial statements and notes to condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto that are included in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission (SEC) on March 16, 2015.

Revenue Recognition

Our revenues are comprised of product sales of Omidria and amounts earned for services under grants from the National Institutes of Health (NIH). Revenue is recognized when there is persuasive evidence that an arrangement exists, product has been shipped to the customer or the service has been provided, the price is fixed or determinable and collection is reasonably assured. We recorded product revenue when title and risk of loss passed to the ASCs, which occurred upon shipment of Omidria. Product sales were made on a direct, non-return basis and as of March 31, 2015, we have not signed any contracts that would create deductions against these sales.

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.

## Table of Contents

### Liquidity and Capital Resources

As of March 31, 2015, we had \$70.1 million in cash, cash equivalents and short-term investments. We believe that our existing cash, cash equivalents and short-term investments and anticipated future sales from Omidria together with capital that we may have the opportunity to raise through public or private equity securities sales, through the issuance of additional debt, through corporate partnerships, through asset sales or through the pursuit of collaborations and licensing arrangements related to certain of our programs will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes for at least the next 12 months. If we are unable to raise capital as and when needed, or upon acceptable terms, such failure would have a significant negative impact on our financial condition.

### Inventory

Inventory is stated at the lower of cost or market determined on a specific identification basis in a manner which approximates the first-in, first-out (FIFO) method. Costs include amounts related to third-party manufacturing, transportation and internal labor and overhead. Capitalization of costs as inventory begins when the product candidate receives regulatory approval in the U.S. or the EU, which for Omidria began upon U.S. regulatory approval in May 2014. We expense inventory costs related to product candidates as research and development expenses prior to regulatory approval in the respective territory. Inventory is reduced to net realizable value by reserving for excess and obsolete inventories based on forecast demand. As of March 31, 2015, all inventory is finished goods for Omidria.

### Segments

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

### Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-03 related to simplifying the presentation of debt issuance costs. This standard requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction to the liability. This standard is effective for interim and annual periods beginning after December 15, 2015 and early adoption is permitted. We are currently evaluating in which period we will transition and the presentation of the debt liability on our balance sheet following such transition, as well as how related disclosures will be impacted. The disclosures required are those applicable for a change in accounting principle.

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

In May 2014, the FASB issued ASU No. 2014-09 related to the recognition of revenue that supersedes existing guidance. This standard clarifies the principles for recognizing revenue utilizing a five-step process. This standard must be applied retroactively to each prior reporting period presented or retrospectively with the cumulative effect of applying the standard recognized in the period adopted. On April 1, 2015, the FASB voted to approve a one-year deferral of the original effective date. This standard is now effective for interim and annual periods beginning after December 15, 2017 and cannot be adopted before that effective date. We are currently evaluating the impact that this standard may have on our financial statements once it is adopted.

### Note 2—Net Loss Per Share

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

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

-7-

---

Table of Contents

	March 31,	
	2015	2014
Outstanding options to purchase common stock	8,365,741	6,762,948
Warrants and pre-funded warrants to purchase common stock	1,160,788	609,016
Total	9,526,529	7,371,964

## Note 3—Cash, Cash Equivalents and Investments

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

## Note 4—Fair-Value Measurements

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

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

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

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

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

	March 31, 2015			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash	\$679	\$—	\$—	\$679
Money-market funds classified as short-term investments	68,621	—	—	68,621
Total	\$69,300	\$—	\$—	\$69,300

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

Cash held in demand deposit accounts of \$1.4 million and \$354,000 is excluded from our fair-value hierarchy disclosure as of March 31, 2015 and December 31, 2014, respectively. There were no unrealized gains and losses associated with our short-term investments as of March 31, 2015 or December 31, 2014. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets for receivables, accounts payable and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

Note 5—Accrued Liabilities

Accrued liabilities consisted of the following:

-8-

---

Table of Contents

	March 31, 2015	December 31, 2014
	(In thousands)	
Consulting and professional fees	\$2,587	\$1,952
Employee compensation	1,893	2,421
Contract research	852	1,280
Clinical trials	619	828
Other accruals	487	589
Total accrued liabilities	\$6,438	\$7,070

## Note 6—Notes Payable

In March 2014, we entered into a Loan and Security Agreement (the Oxford/MidCap Loan Agreement) with Oxford Finance LLC (Oxford) and MidCap Financial SBIC, LP (MidCap) pursuant to which we borrowed \$32.0 million. We used approximately \$19.1 million of the loan proceeds to repay all of the amounts owed by us under our then outstanding loan from Oxford and, after deducting loan initiation costs, we received \$12.7 million in net proceeds. The Oxford/MidCap Loan Agreement provides for interest-only payments at an annual rate of 9.25% through March 1, 2015. Beginning April 1, 2015, monthly principal and interest payments of \$1.0 million became due through the maturity date of March 1, 2018. In addition, the Oxford/MidCap Loan Agreement requires a \$2.2 million loan maturity fee upon full repayment of the loan. We may prepay the outstanding principal balance in its entirety at any time if we pay an additional fee equal to 1.0% of the then-outstanding principal balance, which would be waived if we refinance the indebtedness with Oxford and MidCap and pay the loan maturity fee. As security under the Oxford/MidCap Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property.

The Oxford/MidCap Loan Agreement contains covenants that limit or restrict our ability to enter into certain transactions, and it also includes provisions related to events of default, the occurrence of a material adverse effect (MAE) and changes of control. The occurrence of an event of default could result in the acceleration of the Oxford/MidCap Loan Agreement and, under certain circumstances, could increase our interest rate by 5.0% per annum during the period of default.

As of March 31, 2015, the remaining unamortized discount and debt issuance costs associated with the debt were \$1.5 million and \$227,000, respectively, and are being amortized to interest expense using the effective interest method through the loan maturity date.

## Note 7—Commitments and Contingencies

## Real Estate Obligations

We lease office and laboratory spaces in The Omeros Building. The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of March 31, 2015, the remaining aggregate non-cancelable rent payable under the initial term of the lease was approximately \$57.5 million. The deferred rent balance relates to rent deferrals since the inception of our lease and is being amortized to research and development as well as selling, general and administrative expense on a straight-line basis through the initial term of the lease.

## Contracts

We have an agreement with Ventiv Commercial Services, LLC (inVentiv) for field sales representatives and related sales operation services for the U.S. commercial launch of Omidria. We can terminate the agreement upon 30 days written notice if Omidria is withdrawn from the market for any reason or a regulatory agency acts to prevent or materially restrict the sale of Omidria, or upon 90 days written notice at any time subsequent to January 2016. As of March 31, 2015, our commitment under the agreement is approximately \$630,000 per month 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 March 31, 2015, we had a firm purchase commitment requiring payment of \$879,000.

-9-

---



Table of Contents

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 as of March 31, 2015 and, therefore, we do not currently have any firm purchase commitments outstanding 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 2014 Annual Report on Form 10-K filed with the SEC on March 16, 2015.

**Note 8—Shareholders’ Equity****Common Stock**

**Securities Offerings** - In February 2015, we sold 3.4 million shares of our common stock at a public offering price of \$20.03 and sold pre-funded warrants to purchase up to 749,250 shares of our common stock at a public offering price of \$20.02 per pre-funded warrant share. The public offering price for the pre-funded warrants was equal to the public offering price of the common stock, less the \$0.01 per share exercise price of each pre-funded warrant. If not exercised, the pre-funded warrants will expire on February 3, 2022. After deducting underwriter discounts and offering expenses of \$4.9 million, we received net proceeds from the offering of \$79.1 million.

In March 2014, we sold 3.5 million shares of our common stock at a public offering price of \$11.50 per share. After deducting offering expenses and underwriter discounts of \$2.5 million, we received net proceeds from the transaction of \$37.7 million.

**Warrants**

The following table summarizes our total outstanding warrants as of March 31, 2015, which have a weighted average exercise price of \$10.43:

Outstanding At March 31, 2015	Expiration Date	Exercise Price (\$)
11,539	April 26, 2015	9.13
133,333	October 21, 2015	20.00
133,333	October 21, 2015	30.00
133,333	October 21, 2015	40.00
749,250	February 3, 2022	0.01
1,160,788		

In March 2014 and September 2014, we extended the expiration dates of warrants to purchase approximately 197,000 shares of our common stock at an exercise price of \$12.25 per share by six months that, together, extended the expiration dates of these warrants to March 29, 2015. We evaluated the fair value of the warrants before and after the modifications and for the three months ended March 31, 2014, and we recorded the \$452,000 change in fair value as other expense in the accompanying Condensed Consolidated Statement of Operations and Comprehensive Loss. During the three months ended March 31, 2015, of the warrants with a March 29, 2015 expiration date, warrant holders exercised warrants to purchase 136,017 shares of our common stock, either for cash or pursuant to cashless net exercise provision. Of that amount, 117,231 shares were issued upon cash exercises of warrants, pursuant to which we received proceeds of \$1.4 million, and the remainder were issued pursuant to cashless net exercise provisions.

**Note 9—Stock-Based Compensation**

On January 1, 2015, in accordance with provisions of our 2008 Equity Incentive Plan, the authorized shares available for grant were increased by 1,709,273 shares. As of March 31, 2015, a total of 10,243,574 shares were reserved for

issuance under our stock plans of which 1,877,833 were available for future grants.

-10-

---

Table of Contents

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

	Three Months Ended		
	March 31,		
	2015		2014
Estimated weighted-average fair value	\$13.49		N/A
Weighted-average assumptions			
Expected volatility	70	%	N/A
Expected term, in years	6.0		N/A
Risk-free interest rate	1.51	%	N/A
Expected dividend yield	—	%	N/A

There were no stock option grants during the first quarter of 2014.

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

	Three Months Ended	
	March 31,	
	2015	2014
	(In thousands)	
Research and development	\$1,324	\$1,011
Selling, general and administrative	1,193	777
Total	\$2,517	\$1,788

Stock option activity for all stock plans and related information is as follows:

	Options Outstanding	Weighted-Average Exercise Price per Share	Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2014	8,364,469	\$7.52		
Granted	84,325	21.46		
Exercised	(69,004 )	2.02		
Forfeited	(14,049 )	12.19		
Balance at March 31, 2015	8,365,741	\$7.70	6.80	\$119,875
Vested and expected to vest at March 31, 2015	8,075,479	\$7.58	6.73	\$116,713
Exercisable at March 31, 2015	5,447,791	\$5.90	5.65	\$87,848

At March 31, 2015, there were 2,917,950 unvested options outstanding that will vest over a weighted-average period of 2.4 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these options is \$17.2 million.

Table of Contents

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

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

Overview

We are a biopharmaceutical company committed to discovering, developing and commercializing both small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Our marketed drug product Omidria is approved in the U.S. for use during cataract surgery or intraocular lens, or IOL, replacement surgery, to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. Omidria is derived from our proprietary PharmacoSurgery® platform, which is designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures. Our proprietary PharmacoSurgery® platform is based on low-dose combinations of U.S. Food and Drug Administration-approved, or FDA-approved, therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. We also have six clinical-stage development programs in our pipeline, which includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor, or GPCR, drug targets and the other used to generate antibodies. For Omidria and each of our product candidates and our programs, we have retained all manufacturing, marketing and distribution rights.

Products, Product Candidates and Development Programs

Commercial Product

Omidria is approved by the FDA for use during cataract surgery or IOL replacement surgery. The Centers for Medicare and Medicaid Services, or CMS, has granted transitional pass-through reimbursement status for Omidria, which we expect to run through December 31, 2017. Pass-through status allows for separate payment under Medicare Part B for new drugs and other medical technologies that meet well-established criteria specified by federal regulations governing Medicare spending. CMS has set the reimbursement rate for Omidria under Medicare Part B at the product's wholesale acquisition cost, or WAC, of \$465 plus six percent (6%) per single-use vial for the first, second and third quarters of 2015 after which time the rate will be based on average selling price, or ASP, plus six percent (6%). We commenced a controlled launch of Omidria to a small number of ambulatory surgery centers, or ASCs, in the U.S. in February 2015. During the controlled launch, our sales were made on a direct, non-return basis and the majority of the patients were covered under Medicare Part B. In early April 2015, we initiated the broad U.S. launch of Omidria and we have begun to sell the product to wholesalers who will, in turn, sell to ASCs and hospitals. In the EU, we have submitted a Marketing Authorisation Application, or MAA, to the European Medicines Agency, or EMA. We expect to receive an opinion on the MAA from the EMA's Committee for Medicinal Products for Human Use, the scientific committee of the EMA, in the first half of 2015. In the EU and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria.

Product Candidates

We have a pipeline of development programs targeting immune-related disorders, pain, inflammation, coagulopathies and disorders of the central nervous system. We have the following six clinical-stage programs in our pipeline: (1) our lead MASP-2 antibody OMS721, which is in a Phase 2 clinical program in patients with complement-mediated 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 currently suspended pending further evaluation of an observation from a nonclinical study in rats and for which we recently submitted to the FDA a package of nonclinical materials requested by the agency, seeking to re-initiate the OMS824 Phase 2 Huntington's and schizophrenia programs; (3) our Phase 2 program evaluating OMS824 for the treatment of schizophrenia, which is also currently suspended pending such further evaluation; (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 two Phase 2 clinical trials have been conducted by our collaborators to evaluate a PPAR agonist, alone or in combination with other agents, for treatment of addiction

to opioids and to nicotine; 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. OMS721 has received Orphan Drug designation for the prevention (inhibition) of complement-mediated TMAs. 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.

-12-

---

Table of Contents

In February 2015, we announced the completion of dosing of the low-dose cohort of patients in a Phase 2 clinical trial evaluating the efficacy and safety of OMS721 in treating thrombotic microangiopathies, or TMAs, including atypical hemolytic uremic syndrome, or aHUS. The second cohort of patients in the Phase 2 clinical trial, who received a higher dose than the first, has also completed treatment. All patients in each study cohort received OMS721, and improvements were observed across a wide range of markers of TMA disease activity. The study's safety committee has recommended that the trial advance to the third cohort at a dose higher than both the first and the second cohorts. Based on the clinical results from the first cohort in this trial, a European investigator requested that Omeros provide extended access to OMS721 for compassionate use in two of the investigator's patients with TMAs. This request has been approved by the presiding European regulatory authority and we have shipped OMS721 to continue treatment of these patients. Similarly, based on the clinical results from the second cohort in this trial, another European investigator has requested that Omeros provide extended access to OMS721 for compassionate use in the investigator's patient with TMA. Efforts are underway in this second country to obtain the approvals necessary to make OMS721 available to the investigator for patient use.

**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 OMS906 program in which we are developing MASP-3 inhibitors for the treatment of disorders related to the alternative pathway of the complement system; and (4) our GPR17 program in which we are identifying inhibitors of GPR17, an orphan GPCR linked to myelin formation. We also have two additional platforms: one used to generate antibodies and the other capable of unlocking new G protein-coupled receptor, or GPCR, drug targets.

**Financial Summary**

We recognized net losses of \$18.7 million and \$16.6 million for the three months ended March 31, 2015 and 2014, respectively. As of March 31, 2015, our accumulated deficit was \$346.7 million, total shareholders' equity was \$21.8 million and we had \$70.1 million in cash, cash equivalents and short-term investments.

**Results of Operations****Revenue**

Our revenue consists of net product sales of Omidria, which began in February 2015, and revenue recognized in connection with grant funding from third parties.

	Three Months Ended March 31,	
	2015	2014
	(In thousands)	
Product sales	\$238	\$—
Small Business Innovative Research (SBIR) Grants	150	100
Total Revenue	\$388	\$100

The increase in revenue during the three months ended March 31, 2015 compared to the prior year quarter was primarily due to the initial U.S. sales of Omidria. In February 2015 we commenced a controlled launch of Omidria, during which we sold Omidria on a direct, non-return basis to a small number of ASCs in the U.S. A majority of the patients involved were covered under Medicare Part B. As of March 31, 2015, we had not entered into any contracts that would create deductions against these product sales.

**Research and Development Expenses**

Our research and development expenses can be divided into three categories: direct external expenses, which include clinical research and development and preclinical research and development activities; internal, overhead and other expenses; and stock-based compensation expense. Direct external expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations, contract research organizations, or CROs, clinical trial sites, collaborators, licensors and consultants and lab supplies. Costs are reported in preclinical research

and development until the program enters the clinic. Internal, overhead and other expenses consist of personnel costs, overhead costs such as rent, utilities and depreciation and other miscellaneous costs. We do not generally allocate our internal resources, employees and infrastructure to

-13-

---

Table of Contents

any individual research project because we deploy them across multiple clinical and preclinical projects that we are advancing in parallel.

The following table illustrates our expenses associated with these activities:

	Three Months Ended March 31,	
	2015	2014
	(In thousands)	
Direct external expenses:		
Clinical research and development:		
OMS721	\$1,233	\$2,033
Omidria	754	1,139
OMS824	532	3,620
Other clinical programs	17	24
Total clinical research and development	2,536	6,816
Preclinical research and development	501	312
Total direct external expenses	3,037	7,128
Internal, overhead and other expenses	4,957	3,878
Stock-based compensation expense	1,324	1,011
Total research and development expenses	\$9,318	\$12,017

The decrease in total research and development expenses during the three months ended March 31, 2015 compared to the same period in 2014 was due primarily to lower manufacturing costs for the OMS824 and OMS721 clinical programs. Clinical material was manufactured during the first quarter of 2014 for trials for the Phase 1 and Phase 2 clinical programs evaluating OMS824 for the safety, tolerability and pharmacokinetics and for the treatment of Huntington's disease, respectively, each of which began in the first half of 2014. Clinical material was also manufactured during the first quarter of 2014 for the Phase 2 clinical program evaluating OMS721 for the inhibition of complement-mediated TMAs, which began in the first quarter 2014 and is ongoing. Additional decreases in the current quarter included lower clinical trial costs for both our Phase 1 and Phase 2 clinical programs evaluating OMS824 due to the suspension of clinical enrollment in our OMS824 clinical programs by the FDA. These decreases were partially offset by an increase in internal, overhead and other expenses related to employee costs primarily due to increased headcount. We anticipate research and development costs will increase during the remainder of this year due to planned clinical manufacturing and clinical study activities.

At this time, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates due to the inherently unpredictable nature of our preclinical and clinical development activities and given the early stage of many of our preclinical development programs. Clinical development timelines, the probability of success and development costs can differ materially as expectations change. While we are focused currently on advancing our product development programs, our future research and development expenses will depend, in part, on the preclinical or clinical success of each product candidate as well as ongoing assessments of each program's commercial potential. Our future research and development expenses might also depend on the commercial success of Omidria. In addition, we cannot forecast with any degree of certainty which product candidates, if any, may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

We are required to expend substantial resources in the development of our product candidates due to the lengthy process of completing clinical trials and seeking regulatory approval. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could delay our generation of product revenue and increase our research and development expenses and, in turn, have a material adverse effect on our operations, financial condition and liquidity. Because of the factors above, we are not able to estimate with any certainty when or if we would recognize any net cash inflows from our research and development projects.





Table of Contents

## Selling, General and Administrative Expenses

	Three Months Ended March 31,	
	2015	2014
	(In thousands)	
Selling, general and administrative expenses, excluding stock-based compensation expense	\$7,796	\$2,990
Stock-based compensation expense	1,193	777
Total selling, general and administrative expenses	\$8,989	\$3,767

The increase in selling, general and administrative expenses during the three months ended March 31, 2015 compared to the same period in 2014 was primarily due to sales and marketing costs incurred in anticipation of the U.S. commercial launch of Omidria. We initiated launch-related sales and marketing activities in the second quarter of 2014 and continued to increase those activities through the quarter ended March 31, 2015.

## Interest Expense

	Three Months Ended March 31,	
	2015	2014
	(In thousands)	
Interest expense	\$957	\$672

The increase in interest expense during the three months ended March 31, 2015 was due to a higher average balance on our note payable during the 2015 period following our entry into the Loan and Security Agreement, or the Oxford/MidCap Loan Agreement, with Oxford Finance LLC, or Oxford, and MidCap Financial SBIC, LP, or MidCap, in March 2014. We increased the aggregate amount of our outstanding indebtedness by approximately \$12.7 million as a result of entering into this agreement.

## Investment Income and Other Income (Expense), Net

	Three Months Ended March 31,	
	2015	2014
	(In thousands)	
Investment income and other income (expense), net	\$218	\$(286)

Investment income and other income (expense), net includes investment and interest income, sublease rental income and non-cash charges associated with warrant modifications. The balance in investment income and other income (expense), net for the three months ended March 31, 2015 compared to the same quarter in the prior year, was primarily related to sublease rental income and a \$452,000 expense charge incurred as a result of our extending the exercise period of warrants to purchase 197,000 shares of our common stock in March 2014 by six months.

## Financial Condition - Liquidity and Capital Resources

As of March 31, 2015, we had \$70.1 million in cash, cash equivalents and short-term investments that are held principally in interest-bearing instruments, including money-market accounts. Cash in excess of our immediate requirements is invested in accordance with established guidelines intended to preserve principal and maintain liquidity.

We believe that our existing cash, cash equivalents and short-term investments and anticipated future sales from Omidria, together with capital that we may have the opportunity to raise through public or private equity securities sales, through the issuance of additional debt, through corporate partnerships, through asset sales or through the pursuit of collaborations and licensing arrangements related to certain of our programs, will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes for at least the next 12 months. If we are unable to raise capital as and when needed, or upon acceptable terms, such failure would have a significant negative impact on our financial condition.



Table of Contents

	Three Months Ended March 31,	
	2015	2014
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	\$(17,476 )	\$(11,139 )
Investing activities	(62,089 )	(38,911 )
Financing activities	80,652	49,233

Operating Activities. Net cash used in operating activities increased by \$6.3 million for the three months ended March 31, 2015 compared to the same period in 2014. This increase was in part due to our net loss increasing by \$2.0 million, primarily due to increased sales and marketing expenses related to preparing for the U.S. commercial launch of Omidria, partially offset by reduced research and development expenses. During the first quarter of 2015 compared to the prior year quarter, our non-cash charges increased by \$335,000 due to an increase in stock compensation expense that was greater than the decrease in the warrant modification expense. Cash used during the first quarter of 2015 increased by \$4.6 million compared to the same period in 2014 due to the net change in operating assets and liabilities.

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

Net cash used in investing activities in the three months ended March 31, 2015 was \$62.1 million, an increase of \$23.2 million from 2014, primarily due to the purchase of short-term investments with the \$79.1 million of net proceeds received from the sale of common stock and pre-funded warrants in our public offering in February 2015. These purchases were partially offset by the sale of \$17.3 million of short-term investments to provide cash for operating activities.

Financing Activities. Net cash provided by financing activities in the three months ended March 31, 2015 was \$80.7 million, an increase of \$31.4 million over the same quarter in 2014 primarily due to the \$79.1 million of net proceeds received from the sale of 3.4 million shares of common stock and pre-funded warrants to purchase 749,250 shares of common stock in our public offering in February 2015. Additionally, we received \$1.3 million in incremental proceeds compared to the prior year quarter from the exercise of warrants with an expiration date of March 29, 2015 as well as stock options. During the 2014 period, cash was provided by the \$37.7 million of net proceeds from the sale of 3.5 million shares of common stock in our public offering and the net additional borrowings of \$12.7 million under the Oxford/MidCap Loan Agreement. During the period, from January 2014 to March 2014, we paid \$1.5 million of principal on the then outstanding Oxford notes. For the three months ended March 31, 2015, no principal payments were made on the Oxford/MidCap notes as the agreement provided for interest-only payments from its March 2014 inception until April 1, 2015.

## Contractual Obligations and Commitments

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

	Payments Due Within				
	1 Year	2-3 Years	4-5 Years	More than 5 Years	Total
	(In thousands)				
Operating leases	\$4,023	\$8,303	\$8,652	\$36,605	\$57,583
Capital leases (principal and interest)	54	106	37	—	197

Edgar Filing: OMEROS CORP - Form 10-Q

Notes payable (principal and interest)	12,256	24,512	—	—	36,768
Goods & services	6,986	643	—	—	7,629
Total	\$23,319	\$33,564	\$8,689	\$36,605	\$102,177

-16-

---

## Table of Contents

### Operating Leases

We lease our office and laboratory space in The Omeros Building under a lease agreement with BMR-201 Elliott Avenue LLC. The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of March 31, 2015, the remaining aggregate non-cancelable rent payable under the initial term of the lease was approximately \$57.5 million.

### Notes Payable

We have borrowed \$32.0 million under the Oxford/MidCap Loan Agreement that requires interest-only payments at an annual rate of 9.25% through March 2015. Beginning April 1, 2015, monthly principal and interest payments of \$1.0 million 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.

### Goods & Services

In June 2014, we entered into an agreement with Ventiv Commercial Services, LLC, or inVentiv, for field sales representatives and related sales operation services for the U.S. commercial launch of Omidria. In October 2014, we amended the agreement to add additional sales representatives in the U.S. As of March 31, 2015, we had a monthly commitment of approximately \$630,000 under the agreement and related amendment. We can terminate the agreement upon 30 days written notice if Omidria is withdrawn from the market for any reason or a regulatory agency acts to prevent or materially restrict the sale of Omidria, or upon 90 days written notice at any time subsequent to January 2016. The estimated costs for this agreement through January 2016 are included in the table above.

We have a non-exclusive agreement with Patheon Manufacturing Services LLC, or Patheon, for commercial supply of Omidria through December 31, 2015. We are required to provide a monthly, non-binding production forecast covering the term of the contract. Upon submission of the monthly forecast, a portion of the forecast becomes a firm purchase commitment. In the event we do not purchase the quantities included in the firm purchase commitment, we would owe a cancellation fee. The firm purchase commitment of \$879,000 as of March 31, 2015 is included in the table above.

In 2014, we entered into an agreement with Catalent Pharma Solutions, or Catalent, for cGMP manufacturing of OMS721. This agreement is subject to the terms and conditions of the Development and Master Services Agreement between the two parties, executed in December 2011. Under the terms of this agreement, if we cancel the production of the substance prior to the slot reservation date, we would owe a cancellation fee based on a percentage of the total batch cost dependent on the date Catalent is notified of the cancellation. As of March 31, 2015, we would owe a payment of approximately \$396,000, which is included in the table above.

We may also be required, in connection with in-licensing or asset acquisition agreements, to make certain royalty and milestone payments and we cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. Therefore, such payments are not included in the table above. See Note 8 to our Consolidated Financial Statements in our 2014 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 16, 2015 for a description of the agreements that include these royalty and milestone payment obligations.

### Critical Accounting Policies and Significant Judgments and Estimates

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

### Revenue Recognition

During the quarter ended March 31, 2015, we began selling Omidria, our first commercial product, on a controlled basis directly to a small number of ASCs in the U.S. We recorded revenue when title and risk of loss passed to the ASCs, which occurred upon shipment of Omidria. These product sales were made on a direct, non-return basis and as

of March 31, 2015, we have not signed any contracts that would create deductions against these sales. For a more detailed listing of our other critical accounting policies and significant judgments and estimates, refer to our 2014 Annual Report on Form 10-K filed with the SEC on March 16, 2015.

-17-

---

Table of Contents

Off-Balance Sheet Arrangements

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

-18-

---



Table of Contents

**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 March 31, 2015, we had cash, cash equivalents and short-term investments of \$70.1 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These securities in our investment portfolio are not leveraged and are classified as available-for-sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates and with our current portfolio of short term investments, we are not exposed to potential loss due to changes in interest rates.

**ITEM 4. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

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

**Changes in Internal Control over Financial Reporting**

During the first quarter of 2015, we began selling Omidria in the U.S. We have engaged a third party logistics provider to perform a variety of functions related to the U.S. commercialization of Omidria including inventory management, sales processing and distribution, invoicing and collections and certain accounting functions. We use the provider's systems to obtain inventory, sales and accounting information. In connection with these functions, we designed and implemented internal systems and controls associated with the product launch. Other than these changes related to the Omidria launch, there were no changes 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.

Table of Contents

PART II—OTHER INFORMATION

ITEM 1A. RISK FACTORS

The risks and uncertainties described below may have a material adverse effect on our business, prospects, financial condition or operating results. In addition, we may be adversely affected by risks that we currently deem immaterial or by other risks that are not currently known to us. You should carefully consider these risks before making an investment decision. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2014.

Risks Related to Our Products, Programs and Operations

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

Omidria is our only product that has been approved by the FDA for commercial sale in the U.S. and we have not yet generated any significant revenue from any product sales to date. We may not be able to successfully commercialize Omidria or any other product candidate, if approved, for a number of reasons, including:

- a lack of acceptance by physicians, patients, third-party payers and other members of the medical community;
- our limited experience in marketing, selling and distributing Omidria or any other product;
- our limited experience managing third-party commercial manufacturing of Omidria or any other product;
- our reliance on a limited number of manufacturers and our reliance on a limited number of suppliers of the product's active pharmaceutical ingredients, excipients and packaging materials;
- reimbursement and coverage policies of government and private payers such as Medicare, Medicaid, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- the availability, relative price and efficacy of the product as compared to alternative treatment options or competing products;
- an unknown safety risk of Omidria or any other product;
- the failure to obtain regulatory approval, including for Omidria in the EU or other foreign territories;
- the failure to enter into and maintain acceptable partnering arrangements for marketing and distribution of Omidria or any other product outside of the U.S.;
- changed or increased regulatory restrictions in the U.S., EU and other foreign territories; and
- a lack of adequate financial or other resources to commercialize the product successfully.

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

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

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

- the level of demand for Omidria;
  - the extent to which coverage and reimbursement for Omidria is available from government and private third-party payers such as Medicare, Medicaid, insurance companies, group purchasing organizations, health maintenance organizations and other plan administrators;
- the continued availability of separate reimbursement for Omidria once transitional pass-through reimbursement expires;
- the timing, cost and level of investment in our sales and marketing efforts to support Omidria sales;
- the 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.

-20-

---

Table of Contents

Further, the number of procedures in which Omidria would be used, or the size of the market in which any other of our products would be used, if commercialized, may be significantly less than the total number of such procedures performed or total possible market size. Our revenues may also depend on commercial arrangements, development funding and the achievement of development and clinical milestones under collaboration and license agreements that we may enter into from time to time in the future. 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.

If we do not have adequate reimbursement from governments or other third-party payers 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 payers, 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 payer may depend on a number of factors, including the third-party payer's determination that use of a product is:

- 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 payer can be a time-consuming and costly process that will require the build-out of a sufficient staff or the engagement of third parties and could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our approved products to each payer. We can provide no assurances at this time regarding the cost-effectiveness of Omidria 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. Even if one payer adopts a favorable reimbursement methodology for Omidria or any of our product candidates, if commercialized, there is no guarantee that other third-party payers will adopt the same methodology. For example, other third-party payers often follow, but are not required to follow, the reimbursement methodology adopted by CMS.

There may be significant delays in obtaining reimbursement for newly approved products, and we may not be able to provide data sufficient to be granted reimbursement. Even when a payer determines that a product is eligible for reimbursement, coverage may be limited to the uses of a product that are either approved by the FDA or foreign regulatory agencies and/or appear in a recognized drug compendium, and other conditions may apply. Increasingly, third-party payers who reimburse healthcare costs, such as government and private payers, are requiring that companies provide them with predetermined discounts from list prices and challenging the prices charged for medical products. 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 that pass-through reimbursement status for Omidria will last until December 31, 2017. After pass-through reimbursement status expires, we may not be able to maintain or obtain separate reimbursement for Omidria.

In non-U.S. jurisdictions, we must obtain separate reimbursement approvals and comply with related foreign legal and regulatory requirements. In some countries, including those in the EU, our products may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time and

expenditure of resources after the receipt of marketing approval for a product. We provide no assurances that the price of any product in one or more of these countries or regions will allow us to make a profit or cover our costs, including research, development, manufacturing, sales and distribution, and as a result we may decide to delay, potentially indefinitely, initiating sales in the particular country or region.

If the reimbursement that we are able to obtain and maintain for any product that we develop, including Omidria, is inadequate in light of our development and other costs or is significantly delayed, our business could be materially harmed.

## Table of Contents

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

Prior to the U.S. launch of Omidria, Omeros had never sold, marketed or distributed any 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 or continued product sales. 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 no experience operating or managing a third-party sales force for any product. We also have limited experience in managing distribution for any product and intend to rely on third parties for many of these services for Omidria in the U.S. Factors that may inhibit our efforts to commercialize any approved products, including Omidria, include:

- our inability to recruit in a timely manner and retain and manage adequate numbers of effective sales and marketing personnel, or to partner or contract with, and manage, 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;
- 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 and/or maintaining a sales, marketing and distribution organization.

If we are unsuccessful in building or managing a sales and marketing infrastructure internally or through one or more third-party partners for any approved product, or if any of those third-party partners fail to perform as necessary, 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 could 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 our product candidates.

Both before and after approval of any product, we and our suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the U.S. and other countries, covering, among other things, testing, manufacturing, quality control, clinical trials, labeling, advertising, promotion, distribution, and import and export. Failure to comply with applicable requirements could result in, 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 or would be exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials. Obtaining FDA approval of our product candidates requires substantial time, effort, and financial resources, and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on any of our product candidates on a timely basis, if at all.

The FDA may decide that our data are insufficient for approval of our product candidates and require additional preclinical, clinical or other studies or additional work related to chemistry, manufacturing and controls. For example, we suspended 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

-22-

---

Table of Contents

manufacturing matters, and our views may, at times, differ from those of the FDA. If we are unable to resolve questions raised by the FDA, we may be required to provide additional information, which may necessitate additional preclinical studies or clinical trials. If we are required to conduct additional 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 approval may be subject to significant limitations on the indicated uses for which that product may be marketed, conditions of use, and/or significant post approval obligations, including additional 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 or a manufacturer's failure to file current cGMPs, 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 criminal penalties, substantial fines or other civil 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 healthcare compliance laws. For example, the Federal Food, Drug and Cosmetic Act and its implementing regulations require 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, and that any product claims be adequately substantiated. 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, including some laws that restrict our interactions with physicians and other providers. Also, if we receive protected patient health information, we may be subject to federal or state privacy laws.

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. In addition, some states mandate that we have a compliance program in place. Implementing an effective compliance program requires the expenditure of significant time and resources. If we are found to be in violation of any of these laws, 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.

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



Our operations have consumed substantial amounts of cash since we were incorporated in June 1994. As of March 31, 2015, we had an accumulated deficit of approximately \$346.7 million. We do not anticipate generating significant revenue from the sale of Omidria until the second half of 2015 at the earliest, and we expect to continue to incur additional losses and cannot be certain that we will achieve profitability for some time, if at all. We expect to continue to spend substantial amounts to:

- continue the commercialization of Omidria;
- continue research and development in all of our programs;

-23-

---

Table of Contents

- make principal and interest payments under the Oxford/MidCap Loan Agreement;
- initiate and conduct clinical trials for other programs and product candidates; and
- commercialize and launch any product candidates for which we receive regulatory approval.

If we do not raise additional capital when needed through one or more funding avenues, such as corporate partnering or debt or equity financings, we may be unable to complete these tasks successfully, or at all, which could prevent us from generating sales revenue or limit the amount of sales revenue generated. If we are unable to raise sufficient capital, 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 our products internationally.

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

We have submitted an MAA to 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.” For example, the CHMP may decide not to issue a positive opinion on our application, or the EMA may require us to obtain additional data regarding Omidria and to resubmit our MAA 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 or be commercialized.

Our Phase 3 clinical program evaluating OMS103 in patients undergoing arthroscopic partial meniscectomy demonstrated a drug effect in the first Phase 3 clinical trial by reducing early postoperative pain, which was a secondary endpoint. If we redesign our program to include postoperative pain as the primary endpoint and elect to conduct additional clinical trials with OMS103, we can provide no assurance that in subsequent trials, OMS103 will meet the 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 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 from regulatory authorities, which could cause the market price of our common stock to decline significantly. If we are unable to, or elect not to, complete additional clinical trials for OMS103 or to seek regulatory approval for the marketing of OMS103 and we pursue an alternative approach to make OMS103 commercially available, such as through a registered outsourcing facility, this could cause the market price of our common stock to decline significantly. Potential commercialization of OMS103 by an alternate approach, such as through a registered outsourcing facility, might not succeed or might progress more slowly or generate less revenue than anticipated, which could cause the market price of our common stock to decline significantly.

Table of Contents

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

We intend to rely on third party manufacturers to produce commercial quantities of Omidria and any of our product candidates should they receive regulatory approval. Additionally, we intend to rely on third parties to produce clinical drug supplies needed for clinical trials. We cannot provide any assurance that we will be able to enter into or maintain these types of arrangements on commercially reasonable terms, or at all. If we or the manufacturer were to terminate one of these arrangements early, or the manufacturer was unable to supply product quantities sufficient to meet our requirements, we would be required to transfer the manufacture to an approved alternative facility and/or establish additional manufacturing and supply arrangements. Furthermore, in the event that one of our manufacturers fails to comply with FDA and/or other pharmaceutical manufacturing regulatory requirements, we may need to establish additional or replacement manufacturers, potentially with little or no advance notice. Even if we are able to establish additional or replacement manufacturers, identifying these sources and entering into definitive supply agreements and obtaining regulatory approvals may require a substantial amount of time and cost and may create a shortage of the product. Such alternate supply arrangements may not be available on commercially reasonable terms, or at all. Additionally, if we are unable to engage multiple suppliers to manufacture our products, we may have inadequate supply to meet the demand of our product. Any significant delays in the manufacture of clinical or commercial supplies could materially harm our business and prospects.

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

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

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

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

commercialization of Omidria or those product candidates.

We and our third-party manufacturers must obtain from third-party suppliers the active pharmaceutical ingredients, excipients and primary and secondary packaging materials necessary for our contract manufacturers to produce Omidria and our PharmacoSurgery product candidates for our clinical trials and, to the extent approved, for commercial distribution. Although we have or intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of active pharmaceutical ingredients, excipients and materials for Omidria and our PharmacoSurgery product candidates, we have not yet entered into agreements for the supply of all such ingredients, excipients or materials and we may be unable to secure all such supply agreements or guarantees on commercially reasonable terms, or at all. Even if we were able

-25-

---

Table of Contents

to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients, excipients or materials in a timely manner or in the quantities required. If we or our third-party manufacturers are unable to obtain the quantities of these ingredients, excipients or materials that are necessary for the manufacture of commercial supplies of Omidria, our ability to generate revenue from the sale of Omidria would be materially and adversely affected. Further, if we or our third-party manufacturers are unable to obtain active pharmaceutical ingredients, excipients and materials as necessary for our clinical trials or for the manufacture of commercial supplies of our product candidates, if approved, potential regulatory approval or commercialization would be delayed, which would materially and adversely affect our ability to generate revenue from the sale of our product candidates. If our clinical trials are delayed, we may be unable to develop our product candidates on a timely basis, which will increase our development costs and delay the potential commercialization of our product candidates should they receive regulatory approval.

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

- discussions with the FDA, the EMA or other foreign authorities regarding the scope or design of our clinical trials;
- delays or the inability to obtain required approvals from Institutional Review Boards, Ethics Committees or other responsible entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- lower than anticipated retention rates of patients in clinical trials;
- the need to repeat or conduct additional clinical trials as a result of problems such as inconclusive or negative results, failure to replicate positive early clinical data in subsequent clinical trials, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol or an unacceptable study design;
- adverse findings in clinical or nonclinical studies related to the safety of our product candidates in humans;
- an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval;
- an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials; or
- the placement by a regulatory agency of a trial on a clinical hold.

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

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- the failure to remove a clinical hold in a timely manner (which we cannot predict with certainty) or at all;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial or development program, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may 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.

-26-

---

## Table of Contents

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
- the proximity and availability of clinical trial sites for prospective patients.

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

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

We rely on third parties, such as CROs and research institutions, to conduct a portion of our preclinical research. We also rely on third parties, such as medical institutions, clinical investigators and CROs, to assist us in conducting our clinical trials. Nonetheless, we are responsible for confirming that our preclinical research and clinical trials are conducted in accordance with applicable regulations, the relevant trial protocol and within the context of approvals by an Institutional Review Board or Ethics Committee, and we may not always be successful in ensuring such compliance. Our reliance on these third parties does not relieve us of responsibility for ensuring compliance with FDA and other regulations and standards for conducting, monitoring, recording and reporting the results of preclinical research and clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical and clinical development processes may be extended, delayed, suspended or terminated, and we may not be able to commercialize or obtain regulatory approval for our product candidates.

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

Should we decide to use active pharmaceutical ingredients in any of our product candidates that are proprietary to one or more third parties, we would need to obtain licenses to those active ingredients from those third parties. If we are unable to access rights to these active ingredients prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, we may not be able to commercialize product candidates from these programs.





## Table of Contents

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

Our MASP-2 program is based in part on intellectual property rights that we licensed on a worldwide exclusive basis from the University of Leicester, the UK Medical Research Council at Oxford University and Helion Biotech ApS, or Helion. The continued maintenance of these agreements requires us to undertake development activities and, if regulatory approval for marketing is obtained, to pay royalties to each of these organizations upon commercialization of a MASP-2 product, such as OMS721. In addition, we are obligated to make remaining development and sales milestone payments to Helion of up to \$6.1 million upon the achievement of certain events related to a MASP-2 product, such as the filing of an IND for OMS721 with the FDA, initiation of clinical trials, receipt of marketing approval and reaching specified sales milestones. Our ability to continue development and commercialization of products from our MASP-2 program, including OMS721, depends on our maintaining these exclusive licenses, which cannot be assured.

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

Any product candidate from our MASP-2, MASP-3 or Plasmin programs would be a biologic drug product and we do not have the internal capability to hybridize, clone or manufacture biologics for clinical or commercial use. There are only a limited number of manufacturers of biologic drug products and we cannot be certain that we can enter into supply agreements with them on commercially reasonable terms, if at all. If we are unable to obtain clinical supplies of drug product for one of these programs, clinical trials or the development of any such product candidate for that program could be substantially delayed until we can find and qualify 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 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 unable to develop related product candidates that successfully complete preclinical or clinical testing. If we are unable to develop product candidates, potential corporate partners may be unwilling to enter into partnership agreements with us. We also cannot be certain that any product candidates that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

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

Because we have limited resources, we must focus on the product candidates and clinical and preclinical development programs that we believe are the most promising. As a result, we may forego or delay the pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential and may not be able to progress development programs as rapidly as otherwise possible. Our resource allocation decisions may cause us to fail to capitalize on viable potential commercial products or profitable market opportunities. Further, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish

valuable rights to that product through collaboration, license or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

-28-

---

## Table of Contents

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;
- 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.

## Table of Contents

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

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

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 cannot be certain that third-party patents containing claims covering our products, product candidates, programs, technologies or methods do not exist, have not been filed, or could not be filed or issued. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the capital necessary to continue our operations.

The terms of our debt facility place restrictions on our operating and financial flexibility and, if we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business. We have borrowed \$32.0 million pursuant to the terms of the loan and security agreement with Oxford and MidCap entered into in March 2014. As collateral for this loan, we pledged substantially all of our assets other than intellectual property. The Oxford/MidCap Loan Agreement restricts our ability to incur additional indebtedness, pay dividends, pledge our intellectual property and engage in significant business transactions such as a change of control of Omeros.

Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. In addition, if we default under the Oxford/MidCap Loan Agreement, the lenders may have the right to accelerate all of our repayment obligations under the Oxford/MidCap Loan Agreement and to take control of our pledged assets, which include our cash, cash equivalents and short-term investments, potentially requiring us to renegotiate the Oxford/MidCap Loan Agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. An event of default under

-30-

---

Table of Contents

the Oxford/MidCap Loan Agreement includes the occurrence of any material adverse effect upon our business operations, properties, assets, results of operations or financial condition, taken as a whole with respect to our viability, that would reasonably be expected to result in our inability to repay the loan. If either lender declares all obligations under the Oxford/MidCap Loan Agreement immediately due and payable upon the occurrence of any event that the lender interprets as constituting an event of default as defined under the Oxford/MidCap Loan Agreement, including but not limited to the lender concluding that a material adverse change has occurred as defined under the Oxford/MidCap Loan Agreement, we will be required to repay the loan immediately or to attempt to reverse the declaration through negotiation or litigation. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline. If we raise any additional debt financing, the terms of such debt could further restrict our operating and financial flexibility.

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

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

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

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

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

carry insurance, in the event of accidental contamination or injury from these materials, we could be held liable for any damages that result and any such liability could exceed our insurance coverage and other resources.

-31-

---



Table of Contents

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

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

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

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

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

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

We have incurred, and will continue to incur, significant costs associated with compliance with public company reporting and corporate governance requirements, including under the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, as well as rules implemented by the SEC and The Nasdaq Stock Market. The requirements of applicable SEC and Nasdaq rules and regulations may increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. We also expect that these rules and regulations may make it 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. If we are unable to comply with the requirements of Section 404, management may not be able to assess whether our internal control over financial reporting is effective, which may subject us to adverse regulatory consequences and could result in a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we fail to maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner or otherwise comply with the standards applicable to us as a public company. Any failure by us to provide the required financial information in a timely manner could materially and adversely impact our financial condition and the market value of our securities. Cyber-attacks or other failures in telecommunications or IT systems could result in information theft, data corruption and significant disruption of our business operations.

We utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and

-32-

---

Table of Contents

sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effect. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches, and may incur significant additional expense to implement further data protection measures.

**Risks Related to Our Industry**

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

We may not achieve commercial success, particularly if our competitors market products that are safer, more effective, less expensive or faster to reach the market than Omidria or any future products that we may develop and commercialize. Our competitors also may market a product that proves to be unsafe or ineffective, which may affect the market for our competing product, or future product, regardless of the safety or efficacy of our product. For example, compounding pharmacies or registered outsourcing facilities could seek to supply compounded versions of Omidria or OMS103, which could have a material adverse effect on our business and financial condition, and enforcement of our intellectual property to address such activities may consume significant time and resources that could also have a material adverse effect on our business and financial condition. As a further example, other pharmaceutical companies, many with significantly greater resources than we have, are developing PDE10 inhibitors 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. In addition, we believe that other companies are attempting to find compounds that functionally interact with orphan GPCRs. If any of these companies are able to achieve this for a given orphan GPCR before we do, we may be unable to establish a commercially valuable intellectual property position around that orphan GPCR. The failure of Omidria or any other future product that we may market to effectively compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition and results of operations.

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

The pharmaceutical industry is intensely competitive in the markets in which we expect to compete. We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. Our competitors may:

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

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

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

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

-33-

---

Table of Contents

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

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

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

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

We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product's safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with commercialization of our products and product candidates. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain or maintain such insurance on acceptable terms or that we will be able to secure 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 March 31, 2015, our stock traded as high as \$27.64 per share and as low as \$9.76 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 and our ability to partner in the EU with respect to Omidria;
- FDA or foreign regulatory actions related to Omidria or any of our product candidates, including our currently suspended programs evaluating OMS824 for the treatment of Huntington's disease and for the treatment of schizophrenia;
- results from our clinical development programs, including the data from our ongoing clinical development programs evaluating Omidria, OMS721, OMS824, OMS103 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;

-34-

---

Table of Contents

• 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;

• the extent to which we raise funds by issuing equity or debt securities;

• general economic conditions and slow or negative growth of our markets; and

• political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various commercial, scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the commercialization of 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 11.4 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 the holders of these outstanding warrants and/or options to purchase our common stock elect to exercise some or all of them, our shareholders would experience dilution and the market price of our common stock could decline.

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

Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of shareholders to fill board vacancies and the ability of our board of directors to issue preferred stock without shareholder approval. In addition, because we are incorporated in

-35-

---



Table of Contents

Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of shareholders owning 10% or more of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management. We have never declared or paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

Our business requires significant funding, and we have not generated any material revenue. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Additionally, under the Oxford/MidCap Loan Agreement, we have agreed not to pay any dividends so long as we have any outstanding obligations under the agreement. Therefore, we currently do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a rise in the market price of our common stock, which is uncertain and unpredictable, will be the sole source of potential gain for shareholders in the foreseeable future, and an investment in our common stock for dividend income should not be relied upon.

Table of Contents

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

(a) Unregistered Sales of Equity Securities. We issued 125,962 shares of our common stock upon the exercise of warrants to purchase 136,017 shares of our common stock during the three months ended March 31, 2015. We received proceeds of \$1.4 million from the cash exercise of 117,231 warrants upon payment of the cash exercise price of \$12.25 per share. We also issued 8,731 shares of our common stock upon the cashless net exercise of warrants to purchase 18,786 shares of our common stock. 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.

Table of Contents

ITEM 6. EXHIBITS

Exhibit Number	Description
4.1(1)	Form of Omeros Corporation Pre-Funded Warrant to Purchase Common Stock
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

(1) Incorporated by reference to Exhibit VI to Exhibit 10.1 of the registrant's Current Report on Form 8-K filed on February 2, 2015 (File No. 001-34475).

Table of Contents

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: May 11, 2015

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

Dated: May 11, 2015

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