OMEROS CORP
Form 10-Q
May 12, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2014

or

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

For the transition period from to

Commission file number: 001-34475

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

Washington (State or other jurisdiction of incorporation or organization)	91-1663741 (I.R.S. Employer Identification Number)
201 Elliott Avenue West Seattle, Washington (Address of principal executive offices) (206) 676-5000 (Registrant's telephone number, including area code)	98119 (Zip Code)

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

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

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

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

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

As of May 7, 2014, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 33,912,447.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our ability to receive regulatory approval for our New Drug Application, or NDA, and our Marketing Authorisation Application, or MAA, for OMS302, or Omidria,™ in the United States and in the European Union, or EU, respectively, in 2014;
- our expectation that the U.S. Food and Drug Administration will approve our NDA for Omidria in the second quarter of 2014;
- our anticipation that we will begin marketing Omidria, if approved, in the U.S. in the second half of 2014, and that we will initiate marketing of Omidria, assuming approval of our MAA for Omidria by the European Medicines Agency and partnering in Europe, in the EU in late 2014 or the first half of 2015;
- our plans for sales, marketing and distribution of Omidria in the U.S., EU and other international territories;
- our ability to successfully complete our Phase 2 clinical trials for OMS824 and OMS721;
- our expectation of timing for enrollment of patients in our Phase 2 clinical trial for OMS721;
- our ability to initiate post-marketing studies for Omidria and additional clinical trials for OMS103, should they be necessary;
- whether there may be an opportunity to have OMS103 produced and commercialized by a registered outsourcing facility;
- our expectations regarding the clinical, therapeutic and competitive benefits of our potential products, which we refer to herein as products;
- our estimate regarding how long our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments;
- our ability to raise additional capital through the capital markets or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;
- our expectation that the second half of 2014 is the earliest period in which any of our products will be commercially available or generate revenue;
- our anticipation that we will rely on contract manufacturers to develop and manufacture our products for commercial sale;
- our ability to enter into acceptable arrangements with potential corporate partners;
- whether pediatric studies may afford Omidria an additional six months of exclusivity;
- whether OMS824 has the potential to be delivered as monotherapy or as an adjunct to commercially available antipsychotics;
- whether GPR17 may play a role in re-myelination of neurons and whether GPR17 could be an important drug target in the treatment of demyelinating disorders;
- our expectations about the commercial competition that our products may face;
- our expected financial position, performance, growth, expenses, magnitude of net losses and availability of resources;
- the extent of protection that our patents provide and that our pending patent applications will provide, if patents issue from such applications, for our technologies, programs and products;
- our involvement in potential claims, legal proceedings and administrative actions, the expected course and costs of potential claims, legal proceedings and administrative actions, and the potential outcomes and effects of potential claims, legal proceedings and administrative actions on our business, prospects, financial condition and results of operations; and
-

our estimates regarding our future net losses, revenues, research and development expenses and selling, general and administrative expenses.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part II of this Quarterly Report on Form 10-Q under

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the heading “Risk Factors” and in our other filings with the Securities and Exchange Commission. Given these risks, uncertainties and other factors, actual results or developments anticipated may not be realized or, even if substantially realized, may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of the filing of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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

	March 31, 2014 (unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$567	$ 1,384
Short-term investments	51,622	12,717
Grant and other receivables	488	379
Prepaid expenses	1,312	251
Other current assets	143	86
Total current assets	54,132	14,817
Property and equipment, net	989	939
Restricted cash	679	679
Other assets	267	100
Total assets	$56,067	$ 16,535
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$4,926	$ 2,329
Accrued expenses	5,306	3,944
Current portion of notes payable, net of discount	—	5,600
Total current liabilities	10,232	11,873
Notes payable, net of current portion and discount	32,212	14,898
Deferred rent	8,411	8,148
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Preferred stock, par value $0.01 per share:		
Authorized shares—20,000,000 at March 31, 2014 (unaudited) and December 31, 2013;		
Issued and outstanding shares—none	—	—
Common stock, par value $0.01 per share:		
Authorized shares—150,000,000 at March 31, 2014 (unaudited) and December 31, 2013;		
Issued and outstanding shares—33,901,591 and 30,359,508 at March 31, 2014 (unaudited) and December 31, 2013, respectively	339	304
Additional paid-in capital	275,888	235,685
Accumulated deficit	(271,015)	(254,373)
Total shareholders' equity (deficit)	5,212	(18,384)
Total liabilities and shareholders' equity	$56,067	$ 16,535

See notes to consolidated financial statements

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

	Three Months Ended March 31,	
	2014	2013
Revenue	$100	$1,095
Operating expenses:		
Research and development	12,017	7,127
Selling, general and administrative	3,767	3,988
Total operating expenses	15,784	11,115
Loss from operations	(15,684)	(10,020)
Investment income	2	6
Interest expense	(672)	(587)
Other income (expense), net	(288)	112
Net loss	$(16,642)	$(10,489)
Comprehensive loss	$(16,642)	$(10,489)
Basic and diluted net loss per share	$(0.54)	$(0.40)
Weighted-average shares used to compute basic and diluted net loss per share	30,897,039	25,908,153

See notes to consolidated financial statements

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

	Three Months Ended March 31,	
	2014	2013
Operating activities:		
Net loss	$(16,642)	$(10,489)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of assets	(9)	—
Depreciation and amortization	82	67
Stock-based compensation expense	1,788	1,093
Non-cash interest expense	136	120
Warrant modification expense	452	41
Changes in operating assets and liabilities:		
Grant and other receivables	(109)	(69)
Prepaid expenses and other current and noncurrent assets	(1,060)	(75)
Accounts payable and accrued expenses	3,960	1,227
Deferred revenue	—	(970)
Deferred Rent	263	87
Net cash used in operating activities	(11,139)	(8,968)
Investing activities:		
Purchases of property and equipment	(6)	(88)
Purchases of investments	(58,839)	(3,455)
Proceeds from the sale of investments	19,934	12,250
Net cash provided by (used in) investing activities	(38,911)	8,707
Financing activities:		
Proceeds from issuance of common stock, net of offering costs	37,749	—
Net proceeds from borrowings under notes payable	12,699	—
Payments on notes payable	(1,464)	—
Proceeds from issuance of common stock upon exercise of stock options	249	22
Net cash provided by financing activities	49,233	22
Net decrease in cash and cash equivalents	(817)	(239)
Cash and cash equivalents at beginning of period	1,384	1,520
Cash and cash equivalents at end of period	$567	$1,281
Supplemental cash flow information		
Cash paid for interest	$691	$313

See notes to consolidated financial statements

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OMEROS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced potential product, OMS302 or Omidria™ for lens replacement surgery, is derived from our proprietary PharmacoSurgery® platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures. Our PharmacoSurgery platform is based on low-dose combinations of therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. In addition to Omidria, we have six other clinical-stage development programs in our pipeline, which also includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor (GPCR) drug targets and the other used to generate antibodies. For each of our programs and potential products, which we refer to herein as products, we have retained all manufacturing, marketing and distribution rights.

Omidria is being developed for use in patients undergoing intraocular lens replacement surgery. In July 2013, we submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and in September 2013, we submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Omidria. We expect the FDA to approve our NDA for Omidria in the second quarter of 2014. Assuming approval, we expect to begin marketing Omidria in the U.S. in the second half of 2014. In the European Union (EU) and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria.

Basis of Presentation

Our consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions between and among our subsidiaries have been eliminated. The accompanying unaudited consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of March 31, 2014 and for the three months ended March 31, 2014 and 2013 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Consolidated Balance Sheet at December 31, 2013 has been derived from audited financial statements but does not include all of the information and footnotes required by GAAP.

The accompanying unaudited consolidated financial statements and notes to consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto that are included in our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission (SEC) on March 13, 2014.

Use of Estimates

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

Liquidity and Capital Resources

As of March 31, 2014, we had $52.2 million in cash, cash equivalents and short-term investments due, in part, to our recent receipt of the net amounts of $37.7 million from the sale of our common stock and $12.7 million of additional debt financing. We believe that our existing cash, cash equivalents and short-term investments, together with potential sales from Omidria and capital that we may be able to raise through one or more corporate partnerships, equity

offerings, debt financings, collaborations, licensing arrangements or asset sales, will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months.

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Inventory

Capitalization of costs as inventory will begin when the product has received regulatory approval in either the U.S. or the EU. We expense inventory costs related to products as research and development expenses prior to regulatory approval.

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.

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, 2014 and 2013 were computed based on the shares of common stock outstanding during the respective periods. Potentially dilutive securities excluded from the diluted loss per share calculation are as follows:

	March 31,	
	2014	2013
Outstanding options to purchase common stock	6,762,948	5,356,086
Warrants to purchase common stock	609,016	609,016
Total	7,371,964	5,965,102

Note 3—Cash, Cash Equivalents and Investments

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

Note 4—Fair-Value Measurements

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

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

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

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

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

	March 31, 2014			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as cash equivalents	$—	$—	$—	$—
Money-market funds classified as non-current restricted cash	679	—	—	679
Money-market funds classified as short-term investments	51,622	—	—	51,622
Total	$52,301	$—	$—	$52,301

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

Cash held in demand deposit accounts of $567,000 and $1.2 million is excluded from our fair-value hierarchy disclosure as of March 31, 2014 and December 31, 2013, respectively. There were no unrealized gains and losses associated with our short-term investments as of March 31, 2014 or December 31, 2013. The carrying amounts reported in the accompanying Consolidated Balance Sheets for grant and other receivables, accounts payable and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

Note 5—Accrued Liabilities

Accrued liabilities consisted of the following:

	March 31, 2014	December 31, 2013
	(In thousands)	
Contract research	$1,727	$858
Employee compensation	1,476	1,346
Clinical trials	768	596
Consulting & professional fees	971	649
Other accruals	364	495
Total accrued liabilities	$5,306	$3,944

Note 6—Notes Payable

In March 2014, we entered into a new Loan and Security Agreement (the Oxford/MidCap Loan Agreement) with Oxford Finance LLC (Oxford) and MidCap Financial SBIC, LP (MidCap) pursuant to which we borrowed $32.0 million. We used approximately $19.1 million of the loan proceeds to repay all of the amounts owed by us under our then outstanding loan from Oxford and, after deducting all loan initiation costs including a $160,000 upfront loan initiation fee and lenders' legal costs, we received $12.7 million in net proceeds. The Oxford/MidCap Loan Agreement provides for monthly interest-only payments at an annual rate of 9.25% through March 1, 2015. Beginning April 1, 2015, monthly principal and interest payments of $1.0 million are due through the maturity date of March 1, 2018. In addition, the Oxford/MidCap Loan Agreement requires a $2.2 million loan maturity fee upon full repayment of the loan. We may prepay the outstanding principal balance in its entirety at any time if we pay an additional fee equal to 1.0% of the then-outstanding principal balance, which prepayment fee would be waived if we refinance the indebtedness with Oxford and MidCap and pay the loan maturity fee. As security under the Oxford/MidCap Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property.

The Oxford/MidCap Loan Agreement contains covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, pledge our intellectual property or repurchase stock. Additionally, the Oxford/MidCap Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breach, occurrence of a material adverse effect (MAE, as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgment defaults and a change of control. The occurrence

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

MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our

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inability to repay any portion of the loans in accordance with the terms of the Oxford/MidCap Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the enforceability of any material provision of the Oxford/MidCap Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce its rights and remedies under the Oxford/MidCap Loan Agreement or related agreements.

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

As of March 31, 2014, the remaining unamortized discount and debt issuance costs associated with the debt were $2.2 million and $339,000, respectively.

Note 7—Revenue

Revenue recognized from grants and other sources is as follows:

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Small Business Innovative Research Grants	$100	$125
Vulcan Inc.	$—	$970
Total revenue	$100	$1,095

We have periodically received Small Business Innovative Research (SBIR) grants from the National Institutes of Health (NIH), which are used to support the research and development of our products. We recorded revenue related to these grants of $100,000 and $125,000 for the three months ended March 31, 2014 and 2013, respectively. As of March 31, 2014, $1.1 million of potential revenue remained available under these grants, if qualifying research is performed.

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

Note 8—Commitments and Contingencies

Real Estate Obligations

We currently lease our office and laboratory space in The Omeros Building under a lease agreement with BMR-201 Elliott Avenue LLC (BMR). The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of March 31, 2014, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately $61.0 million. The remaining deferred rent balance relates to rent deferrals since the inception of our lease. Deferred rent is being amortized to research and development and selling, general and administrative expense on a straight-line basis through the term of the lease.

Development Milestones and Product Royalties

We have retained the worldwide commercial rights to all of the products in our clinical and preclinical programs. We potentially owe certain development milestones and sales based royalties on commercial sales of certain products within our pipeline. These are low-single-digit royalties based on net sales or net income as more fully described in our 2013 Annual Report on Form 10-K filed with the SEC on March 13, 2014.

In April 2010, we entered into an exclusive license agreement with Helion Biotech ApS (Helion), pursuant to which we received a royalty-bearing, worldwide exclusive license to all of Helion's intellectual property rights related to mannan-binding lectin-associated serine protease-2 (MASP-2) antibodies, polypeptides and methods in the field of

inhibition of mannan-binding lectin-mediated activation of the complement system for the prevention, treatment or diagnosis of any disease or condition. We

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incurred a milestone payment of $200,000 to Helion during the first quarter of 2014 related to the filing of an Investigational New Drug Application (IND) with the FDA.

Other

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

Note 9—Shareholders' Equity

Common Stock

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

MLV At-the-Market Sales Agreement - In December 2012, we entered into an at-the-market issuance sales agreement (the Sales Agreement) with MLV & Co. LLC (MLV). The Sales Agreement terminated April 16, 2014.

Warrants

The following table summarizes our total outstanding warrants as of March 31, 2014, which have a weighted average exercise price of $23.85:

Outstanding At March 31, 2014	Expiration Date	Exercise Price
197,478	September 29, 2014	$12.25
133,333	October 21, 2015	20.00
133,333	October 21, 2015	30.00
133,333	October 21, 2015	40.00
11,539	April 26, 2015	9.13
609,016		$23.85

On March 28, 2014, we extended the expiration dates of warrants to purchase 197,478 shares of our common stock at an exercise price of $12.25 per share to September 29, 2014. In March 2013, we extended the expiration dates of the same warrants by one year. We evaluated the fair value of the warrants before and after the modifications and recorded the $452,000 and $41,000 change in fair value as other expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the three months ended March 31, 2014 and 2013, respectively.

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

Note 10—Stock-Based Compensation

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

On January 1, 2014, in accordance with provisions of the 2008 Plan, the authorized shares available for grant under the 2008 Plan were increased by 1,517,975 shares. As of March 31, 2014, a total of 8,858,525 shares were reserved for issuance under our stock plans, of which 2,095,577 were available for future grants under the 2008 Plan.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. There were no stock option grants during the first quarter of 2014 or 2013.

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

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Research and development	$1,011	$581
Selling, general and administrative	777	512
Total	$1,788	$1,093

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

	Options Outstanding	Weighted-Average Exercise Price per Share	Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2013	6,969,303	$6.38		
Granted	—	—		
Exercised	(42,083)	5.93		
Forfeited	(164,272)	9.80		
Balance at March 31, 2014	6,762,948	$6.30	6.83	$39,056
Vested and expected to vest at March 31, 2014	6,526,397	$6.20	6.75	$38,315
Exercisable at March 31, 2014	4,322,288	$4.78	5.63	$31,509

At March 31, 2014, there were 2,440,660 unvested options outstanding that will vest over a weighted-average period of 2.3 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these options is $12.9 million.

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

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

Overview

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced potential product, OMS302 or Omidria™ for intraocular lens replacement, or ILR, is derived from our proprietary PharmacoSurgery® platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures. Our PharmacoSurgery platform is based on low-dose combinations of therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. In addition to Omidria, we have six other clinical-stage development programs in our pipeline, which also includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor, or GPCR, drug targets and the other used to generate antibodies. For each of our programs and potential products, which we refer to herein as products, we have retained all manufacturing, marketing and distribution rights.

Products and Development Programs

We submitted for Omidria a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, in July 2013 and a Marketing Authorisation Application, or MAA, to the European Medicines Agency, or EMA, in September 2013 to allow us to market and sell Omidria in the U.S. and the European Union, or EU, respectively, for use in patients undergoing ILR. In October 2013, we announced that the FDA accepted the NDA for Omidria for filing and that the MAA for Omidria was validated by the EMA. We expect the FDA to approve our NDA for Omidria in the second quarter of 2014. Assuming approval, we expect to begin marketing Omidria in the U.S. in the second half of 2014. In November 2013, the FDA conditionally accepted Omidria as the proposed brand name for OMS302 in the U.S. and in December 2013, the EMA accepted Omidria as the proposed brand name for OMS302 in the EU. These acceptances are subject to final determination prior to approval of the respective marketing applications. For the potential commercial launch of Omidria in the U.S., if approved, we intend to develop our own internal sales and marketing management team and to utilize marketing consultants and a contract sales organization to call on surgeons, hospitals and ambulatory surgery centers in the U.S. In the EU and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria. Assuming approval of our MAA for Omidria by the EMA and partnering in Europe, we anticipate the initiation of EU marketing and sales of Omidria in late 2014 or in the first half of 2015. We have discussed with the FDA and EMA the design for pediatric studies for Omidria, which may afford Omidria an additional six months of exclusivity in each of these territories if completed successfully. In addition, we are exploring the potential role of Omidria in the management of intraoperative floppy iris syndrome, or IFIS.

Behind Omidria in our pipeline, we have a series of other development programs targeting pain, inflammation, coagulopathies and disorders of the central nervous system. We have the following six additional clinical-stage programs in our pipeline: (1) OMS103 for reducing inflammatory pain following arthroscopic partial meniscectomy, which has completed one Phase 3 trial in patients undergoing this procedure, (2) our lead phosphodiesterase 10, or PDE10, inhibitor OMS824 for the treatment of schizophrenia, which is in a Phase 2 clinical program, (3) our lead PDE10 inhibitor OMS824 for the treatment of Huntington's disease, which is in a Phase 2 clinical program, (4) our lead MASP-2 antibody OMS721, which is in a Phase 2 clinical program in patients with thrombotic microangiopathies, or TMAs, (5) our PPAR program, in which three Phase 2 clinical trials are being conducted by our collaborators to evaluate a PPAR agonist, alone or in combination with other agents, for their effects on smoking, as well as in the abuse liability of oxycodone or heroin and (6) our PharmacoSurgery product OMS201 for use during urological procedures, including uroendoscopic procedures, which has completed a Phase 1/Phase 2 clinical trial in 2010 and is not currently in active clinical trials. Of these six additional clinical programs, we currently are focused on OMS103, OMS824 and OMS721.

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

OMS824 is in two Phase 2 clinical programs, one for schizophrenia and one for Huntington's disease. We are conducting an ongoing Phase 1 clinical program evaluating the safety, tolerability and pharmacokinetics of OMS824 in healthy subjects as

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well as a clinical trial to evaluate target occupancy of OMS824 using PET scans in healthy subjects by measuring the extent to which OMS824 binds to PDE10 in the brain. In January 2014, we announced positive results from our OMS824 Phase 2a clinical trial in which OMS824 was well tolerated and demonstrated comparable tolerability and systemic pharmacokinetics when administered alone and concomitantly with approved antipsychotic agents in patients with stable schizophrenia, opening the potential for OMS824 to be delivered as monotherapy or as an adjunct to commercially available antipsychotics. OMS824 has received Orphan Drug designation for the treatment of Huntington's disease and Fast Track designation for the treatment of cognitive impairment in patients with Huntington's disease. We also are seeking Fast Track designation for OMS824 for schizophrenia.

For OMS721, in February 2014 we reported positive data from our Phase 1 clinical trial. In March 2014, we submitted to the FDA an IND application to evaluate OMS721 in patients with complement-mediated TMAs. That same month, we announced positive data using OMS721 in ex vivo studies of endothelial activation relevant to the pathophysiology of human atypical hemolytic uremic syndrome, or aHUS, a form of TMA. These studies showed that OMS721 significantly inhibited complement deposition in the system using serum samples from aHUS patients obtained during the acute phase of disease ($p<0.01$) and during remission ($p<0.001$) compared to untreated controls. In April 2014, the IND was cleared by the FDA, and a Phase 2 clinical program is currently underway with enrollment of TMA patients expected to begin later this quarter. OMS721 has received Orphan Drug designation for inhibition of complement-mediated TMAs.

Our preclinical programs include: (1) our PDE7 program in which we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders, (2) our Plasmin program in which we are advancing novel antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma as well as for other hyperfibrinolytic states (e.g., liver disease), (3) our proprietary ex vivo antibody platform and (4) our orphan GPCR platform in which we are working to complete high-throughput surrogate de-orphanization of orphan GPCRs, identifying small-molecule compounds that bind and functionally interact with the receptors and to develop products that act at these new potential drug targets. To date, we have identified and confirmed sets of small-molecule compounds that interact selectively with, and modulate signaling of, 54 Class A orphan GPCRs, as well as two Class B GPCRs (glucagon-like peptide-1 receptor, or GLP-1R, and parathyroid hormone 1 receptor, or PTH-1R). We have initiated medicinal chemistry efforts to optimize compounds against several orphan GPCRs including GPR17, which appears to play a critical role in re-myelination of neurons and could be an important drug target in the treatment of demyelinating disorders such as multiple sclerosis as well as traumatic brain and spinal cord injuries.

Financial Summary

The majority of our operating expenses to date have been for research and development activities. Research and development expenses consist of costs associated with research activities as well as costs associated with our product development efforts, which include clinical trial and third-party manufacturing services. Internal research and development costs are recognized as incurred. Third-party research and development costs are expensed at the earlier of when the contracted work has been performed or when upfront and milestone payments are made. Research and development expenses include:

- employee and consultant-related expenses, which include salaries and benefits, and non-cash stock-compensation;
- external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, clinical research organizations, or CROs, clinical trial sites, and collaborators or licensors;
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and depreciation of leasehold improvements and equipment; and
- third-party supplier expenses including laboratory and other supplies.

We recognized net losses of $16.6 million and $10.5 million for the three months ended March 31, 2014 and 2013, respectively. These losses have resulted principally from expenses incurred in connection with research and development activities, consisting primarily of clinical trials, manufacturing services and preclinical studies associated with our current products. Compared to 2013, we expect our net losses to increase as we continue to add personnel for our anticipated growth and to prepare for the commercial launch of Omidria in the U.S., if it is approved, to advance our clinical trials, and expand our research and development efforts. As of March 31, 2014, our accumulated deficit was $271.0 million, total shareholders' equity was $5.2 million and we had $52.2 million in cash, cash equivalents and

short-term investments.

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Results of Operations

Revenue

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Small Business Innovative Research Grant	$100	$125
Vulcan Inc.	—	970
Total Revenue	$100	$1,095

Historically, our revenue has consisted of grant funding and revenue recognized in connection with funding received from third parties. Other than grant funding, we do not expect to receive any revenue from our products unless we receive regulatory approval and commercialize our products or enter into collaborative agreements for the development and commercialization of our products. Omidria, our most advanced product, is currently under review for marketing authorization by both the FDA and the EMA. We expect the FDA to approve our NDA for Omidria in the second quarter of 2014. We do not expect Omidria to be commercially available, if at all, before the second half of 2014 in the U.S. and late in 2014 or in the first half of 2015 in Europe. With respect to the EU, we do not expect to begin marketing Omidria until we have secured a partner with European commercial operations. We continue to pursue government and private grant funding as well as collaboration funding for our products and research programs. The decrease in revenue during the three months ended March 31, 2014 was due to lower revenue recognized from our GPCR program funding agreement with Vulcan Inc. and its affiliate, which we collectively refer to as Vulcan. We recognized the remaining deferred revenue in connection with the Vulcan agreement as revenue in the first quarter of 2013. No further revenue remains to be recognized under the agreement as of March 31, 2014.

Research and Development Expenses

Our research and development expenses can be divided into direct external expenses, which include clinical research and development and preclinical research and development activities; internal, overhead and other expenses; and stock-based compensation expense. The following table illustrates our expenses associated with these activities:

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Direct external expenses:		
Clinical research and development:		
OMS824	$3,620	$374
OMS721	2,033	—
Omidria	1,139	887
OMS103	16	266
Other clinical programs	8	11
Total clinical research and development	6,816	1,538
Preclinical research and development	312	1,600
Total direct external expenses	7,128	3,138
Internal, overhead and other expenses	3,878	3,408
Stock-based compensation expense	1,011	581
Total research and development expenses	$12,017	$7,127

The increase in total research and development expenses during the three months ended March 31, 2014 compared to the same quarter in the prior year was due primarily to higher clinical material manufacturing and clinical expenses related to our Phase 1 and Phase 2 clinical trials evaluating OMS824 for the treatment of schizophrenia and Huntington’s disease, higher clinical material manufacturing and clinical expenses related to our Phase 2 clinical trial

evaluating OMS721 in patients with TMAs, higher expense related to non-cash stock compensation, and higher employee costs. Non-cash stock compensation

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expense increased for the three months ended March 31, 2014 compared to the same period in 2013 due to the grant of stock options during the third quarter of 2013 related to annual performance reviews. These increased expenses for the three months ended March 31, 2014 compared to the same period in 2013 were partially offset by lower clinical research and development expenses related to reduced preclinical activity on our PDE7 program and the completion of our OMS103 Phase 3 clinical trial in December 2012, for which there were costs related to close out during the first quarter of 2013. We expect our research and development expenses to remain constant or increase slightly in the near term as we continue to advance OMS824, OMS721, OMS302 and OMS103 through further clinical development and initiate clinical trials for our Plasmin and PDE7 programs.

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

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

The lengthy process of completing clinical trials and seeking regulatory approval for our products requires the expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations, financial condition and liquidity. We do not expect any of our current products to be commercially available before the second half of 2014, if at all. Because of the factors above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our research and development projects.

Selling, General and Administrative Expenses

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Selling, general and administrative, excluding stock-based compensation expense	$2,990	$3,476
Stock-based compensation expense	777	512
Total selling, general and administrative expenses	$3,767	$3,988

The decrease in selling, general and administrative expenses during the three months ended March 31, 2014 was primarily due to a $900,000 expense recorded in the first quarter of 2013 in connection with previously awarded grants from the National Institutes of Health, or NIH. Exclusive of the NIH expense, selling, general and administrative expenses increased from the first quarter of 2013 compared to the same quarter in 2014. This increase was primarily due to non-cash stock compensation costs and expenses related to the preparation for our planned commercial launch of Omidria in the U.S. We expect our selling, general and administrative expenses to increase in the near term as we prepare for the potential commercial launch of Omidria in the second half of 2014.

Interest Expense

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Interest expense	$672	$587

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The increase in interest expense during the three months ended March 31, 2014 was due primarily to a higher average balance on our note payable during the 2014 period due to entering into a new loan agreement, or the Oxford/MidCap Loan Agreement, with Oxford and MidCap Financial SBIC, LP, or MidCap, in March 2014, pursuant to which we increased the aggregate amount of our outstanding indebtedness.

Other Income (Expense), Net

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Other income (expense), net	$(288)	$112

Other income (expense) principally includes rental income and costs associated with warrant modifications. The decrease in other income (expense) during the three months ended March 31, 2014 is due to an increase in warrant modification expenses from $41,000 in the first quarter of 2013 to $452,000 in the same quarter in 2014 when we extended the exercise period of these warrants by one year and six months, respectively. The warrant modification expenses in each period relate to extensions of the expiration dates of these warrants to purchase up to 197,478 shares of common stock in aggregate.

Financial Condition - Liquidity and Capital Resources

As of March 31, 2014, we had $52.2 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 to preserve principal and maintain liquidity.

In March 2014, we sold 3.5 million shares of our common stock in a public offering at a public offering price of $11.50 per share. After deducting offering expenses and underwriter discounts, we received net proceeds from the transaction of $37.7 million. Also in March 2014, we terminated our existing loan agreement with Oxford and entered into the Oxford/MidCap Loan Agreement, whereby we received $12.7 million in additional funds and deferred the repayment of any principal under the new loan agreement until April 1, 2015.

The audit report covering our 2013 consolidated financial statements contained a “going concern” explanatory paragraph based on our losses and financial condition as of December 31, 2013. Subsequent to the March 13, 2014 issuance of the audit report, we received $37.7 million from the sale of our common stock in the public offering described above. Also as stated above, we received $12.7 million in incremental borrowings under the Oxford/MidCap Loan Agreement in March 2014. We believe that our existing cash, cash equivalents and short-term investments, together with potential sales of Omidria, and funds that we may be able to raise through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales, will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months. If we are unable to raise capital as and when needed, such failure could have a negative impact on our financial condition.

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	$(11,139)	$(8,968)
Investing activities	(38,911)	8,707
Financing activities	49,233	22

Operating Activities. Expenditures related to operating activities were primarily for research and development and selling, general and administrative expenses in support of our operations. Net cash used in operating activities increased for the three months ended March 31, 2014, as compared to the same period in 2013 by $2.2 million,

primarily due to higher operating expenses leading to an increase in our net loss. Other activities impacting the overall increase in net cash used in operating activities between the comparative periods was a $2.7 million increase in accounts payable and accrued expenses, a $985,000 increase in prepaid expenses and other current and noncurrent assets and a $970,000 decrease in deferred revenue.

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Investing Activities. Investing activities, other than the purchases of property and equipment, consist primarily of purchases and sales of short-term investments. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and receipts from the sale of short-term investments, thus causing a shift between our cash and cash equivalents and short-term investment balances. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider these 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, 2014 was primarily due to the purchase of short-term investments with the proceeds we received from the sale of common stock in our public offering and borrowings under the Oxford/MidCap Loan Agreement, both of which occurred in March 2014, and is partially offset by the sale of short-term investments.

Financing Activities. Net cash provided from financing activities in the three months ended March 31, 2014 was due primarily to the $37.7 million of net proceeds that we received from the sale of 3.5 million shares of common stock in our public offering and the net additional borrowings of $12.7 million under the Oxford/MidCap Loan Agreement. During the 2013 period, cash provided by financing activities was due to the $22,000 in net proceeds we received from issuance of common stock upon exercise of stock options. In December 2012, we amended the Oxford notes to provide for interest-only payments through December 31, 2013 and, as a result, for the three months ended March 31, 2013, no cash was used for principal payments on the notes.

Funding Requirements

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

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

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

MLV At-the-Market Agreement

In December 2012, we entered into an at-the-market issuance sales agreement with MLV & Co. LLC, or MLV. This sales agreement expired on April 16, 2014.

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Loan and Security Agreement

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

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

In consideration for the lenders agreeing to provide us with a one-year period of interest-only payments, we will be required to pay the lenders a final payment fee equal to 7.00% of the original principal amount borrowed under the Oxford/MidCap Loan Agreement (i.e., $2.2 million), less any portion of the fee previously paid in connection with a prepayment. We may prepay all or a portion of the outstanding principal and accrued and unpaid interest at any time upon prior notice to the lenders and the payment of a fee equal to 1.00% of the prepaid principal amount in addition to the pro rata portion of the final payment fee attributable to the prepaid principal amount. As security for our obligations under the Oxford/MidCap Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property.

The Oxford/MidCap Loan Agreement contains covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, pledge our intellectual property or repurchase stock. Additionally, the Oxford/MidCap Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breach, occurrence of a material adverse effect, or MAE (as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgment defaults and a change of control. The occurrence of an event of default could result in the acceleration of the Oxford/MidCap Loan Agreement and, under certain circumstances, could increase our interest rate 5.0% per annum during the period of default.

MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our inability to repay any portion of the loans in accordance with the terms of the Oxford/MidCap Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the enforceability of any material provision of the Oxford/MidCap Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce their rights and remedies under the Oxford/MidCap Loan Agreement or related agreements. We considered the MAE definition and believe that the MAE clause has not been triggered as of March 31, 2014.

Contractual Obligations and Commitments

We currently lease our office and laboratory space in The Omeros Building under a lease agreement with BMR-201 Elliott Avenue LLC. The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of March 31, 2014, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately $61.0 million and we have received net lease incentives of $4.6 million, which were recorded as deferred rent on our accompanying consolidated balance sheet.

We may also be required, in connection with in-licensing or asset acquisition agreements, to make certain royalty and milestone payments and we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur. See Note 8 to our consolidated financial statements in our 2013 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC on March 13, 2014 for a description of the agreements that include these royalty and milestone payment obligations.

Critical Accounting Policies and Significant Judgments and Estimates

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S. The preparation of our financial statements requires management to make estimates and assumptions that affect the amounts reported in the

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

In relation to our planned commercial launch of Omidria, capitalization of costs as inventory will begin when Omidria has received regulatory approval in either the U.S. or Europe. We expense inventory costs related to products as research and development expenses prior to regulatory approval.

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

Off-Balance Sheet Arrangements

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

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, 2014, we had cash, cash equivalents and short-term investments of $52.2 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These securities in our investment portfolio are not leveraged and are classified as available-for-sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a materially negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates and, with our current portfolio of short-term investments, we do not believe that we are exposed to potential loss due to changes in interest rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive and financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, as of March 31, 2014. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2014, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

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PART II—OTHER INFORMATION

ITEM 1A. RISK FACTORS

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

Risks Related to Our Products, Programs and Operations

We are focusing a significant portion of our activities and resources on Omidria and our success may largely depend on our ability to obtain regulatory approval.

We are a biopharmaceutical company with no products approved for commercial sale and we have not generated any revenue from product sales. We have incurred, and expect to continue to incur, significant costs relating to the development of our lead PharmacoSurgery product, Omidria, for use during ILR procedures. We intend to focus a significant portion of our activities and resources on gaining regulatory approval and, if approved, commercializing Omidria, and we believe that a substantial portion of the value of our company relates to our ability to obtain marketing approval for and commercialize this product.

We have submitted an NDA with the FDA and an MAA with the EMA for Omidria, and both are currently under review. The regulatory process is subject to substantial agency discretion and risks, including those described later in these risk factors. Either agency may decide not to approve our application, or to require us to obtain additional data regarding Omidria and to resubmit our marketing application(s), further delaying our ability to market and generate revenue from the sale of Omidria.

If there are any negative decisions or delays in the regulatory process, the market price of our common stock could decline significantly.

Even if we receive regulatory approval for Omidria or our other products, we cannot be certain that we will successfully commercialize these products.

We have invested a significant portion of time and financial resources in the development of Omidria and our other products. We anticipate that our ability to generate revenues will depend on the commercial success of our products, including Omidria, if approved, which in turn will depend on several factors, including our ability to:

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

We will continue to incur significant and increasing costs as we continue to support the potential commercial launch of Omidria, if approved. If we fail to commercialize successfully this product or the other products in our pipeline, if approved, or if we are significantly delayed in doing so, we may be unable to generate sufficient revenues to grow our business and our business, financial condition and results of operations will be materially and adversely affected.

Our existing and future products, including Omidria, may never achieve market acceptance.

Even if we receive regulatory approvals for the commercial sale of one or more of our existing or future products, including Omidria, the commercial success of these products will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community. If our products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including:

- our ability to provide acceptable evidence of safety, efficacy and product quality;

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

Further, the number of procedures in which any of our PharmacoSurgery products, if approved, would be used may be significantly less than the total number of such procedures performed. If our products do not receive sufficient levels of acceptance from physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable. If we are unable to increase market penetration of our products, our growth prospects would be significantly harmed.

We are subject to extensive government regulation, including the regulations associated with approval for marketing of our products.

Both before and after approval of our products, we, our products, 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; product recall or seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties. We, the FDA or an independent Institutional Review Board or Ethics Committee may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials.

The FDA has not approved any of our products for sale in the U.S. Obtaining FDA approval requires substantial time, effort, and financial resources, and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on a timely basis, if at all.

The FDA may decide that our data are insufficient for approval of our products and require additional preclinical, clinical or other studies or additional work related to chemistry, manufacturing and controls. As we develop our products, we periodically discuss with the FDA clinical, regulatory and manufacturing matters, and our views may, at times, differ from those of the FDA. For example, the FDA regulates our products that consist of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's claimed effect. The FDA has maintained questions regarding whether available data and information provided to the FDA demonstrate the contribution of each active ingredient in OMS103. We have not yet reached agreement with the FDA regarding clinical trial design, data analysis, and proposed label claims for OMS103. If we are unable to resolve these questions, we may be required to provide additional information, which may include the results of additional preclinical studies or clinical trials.

If we are required to conduct additional clinical trials or other testing of our products 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 products or may never obtain marketing approval.

Even if regulatory approval of a product 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 product. Even after approval, discovery of previously unknown problems with a product, manufacturer, or facility, such as previously undiscovered side effects or adverse effects, may result in restrictions on any product, manufacturer, or facility, including, among other things, a possible withdrawal of approval of the product.

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

We intend to have our products 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. Although we have filed for regulatory approval of Omidria in the EU, we may be unable to file for regulatory approvals in other non-U.S. geographies and may not receive necessary approvals to commercialize Omidria or any of our other products in any market. The 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 may vary from country to country. The time required to obtain regulatory approval outside the U.S. and EU may differ from that required to obtain FDA or EMA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA or EMA approval discussed in these "Risk Factors." We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA or EMA does not ensure approval by regulatory agencies in other jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA or EMA. The failure to obtain these approvals could harm our business.

If we are unable to obtain adequate reimbursement from governments or third-party payors for any products that we may develop or if we are unable to obtain acceptable prices for those products, they may not be purchased or used and, as a result, our prospects for revenue and profitability could suffer.

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

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

Obtaining reimbursement approval for a product from each government or third-party payor can be a time-consuming and costly process that will require the build-out of a sufficient staff or the engagement of consultants and could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. Because none of our products has been approved for marketing, we can provide no assurances at this time regarding their cost-effectiveness and the amount, if any, or method of reimbursement. Further, we can provide no assurance that the amounts, if any, reimbursed to surgical facilities for utilization of our surgery-related products or to surgeons for the administration and delivery of these products will be considered adequate to justify the use of these products. There may be significant delays in obtaining reimbursement coverage for newly approved products and we may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payor determines that a product is eligible for reimbursement, coverage may be limited to the uses of a product that are either approved by the FDA or foreign regulatory agencies and/or appear in a recognized drug compendium, and other conditions may apply. Increasingly, third-party payors who reimburse healthcare costs, such as government and private payors, are requiring that companies provide them with predetermined discounts from list prices and challenging the prices charged for medical products. Moreover, eligibility for coverage does not mean that any product will be reimbursed at a rate that allows us to make a profit in all cases or at a rate that covers our costs, including research, development, manufacturing, sales and distribution. In non-U.S. jurisdictions, we must obtain separate reimbursement approvals and comply with related foreign legal and regulatory requirements. In some countries, including those in the EU, our products may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time and expenditure of resources after the receipt of marketing approval for a product. If the reimbursement that we are able to obtain for any product that we develop is

inadequate in light of our development and other costs or is significantly delayed, our business could be materially harmed.

We cannot be certain that OMS103 will receive regulatory approval.

We are redesigning the Phase 3 clinical program evaluating OMS103 in patients undergoing arthroscopic partial meniscectomy to include postoperative pain reduction as the primary endpoint. While OMS103 demonstrated a drug effect in the first Phase 3 clinical trial by reducing early postoperative pain, which was a secondary endpoint, we can provide no assurance that in subsequent trials, OMS103 will meet the primary endpoint of early postoperative pain reduction or that the

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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, which could cause the market price of our common stock to decline significantly.

We may find it difficult to prevent compounders from preparing compounded formulations of products that may compete with our products when commercialized, including Omidria and OMS103.

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

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate product revenue.

Omeros has never sold, marketed or distributed any biopharmaceutical product. Developing an internal sales force is expensive and time-consuming, and a delay in hiring and training an internal sales force could impact the timing or effectiveness of any product launch. Factors that may inhibit our efforts to commercialize any approved products without commercialization partners include:

- our inability to recruit in a timely manner, and retain, adequate numbers of effective sales and marketing personnel, or to partner or contract with a third party to provide sales and marketing services, in the applicable region of the world, particularly before our planned market launch of Omidria, if approved, in the second half of 2014;
- the inability of sales personnel to sell or promote our product(s) to adequate numbers of hospitals, surgery centers, physicians and/or pharmacists;
- our inability to develop and maintain adequate internal 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 an independent sales and marketing organization.

If we are unsuccessful in building a sales and marketing infrastructure or unable to partner with one or more third parties to perform sales and marketing services for our products, we will have difficulty commercializing our products, which would adversely affect our business and financial condition.

In the EU, we plan to enter into partnerships for Omidria marketing and distribution rights 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. If we are unable to enter into such agreements on terms acceptable to us, or if we are unable to enter into such agreements at all, we would not expect to see sales of Omidria in those territories, which could adversely affect our business and financial condition.

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

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We have not been profitable and have generated substantial operating losses since we were incorporated in June 1994. As of March 31, 2014, we had an accumulated deficit of approximately $271.0 million. We do not anticipate generating revenue from the sale of our products until the second half of 2014 at the earliest and expect to incur additional losses for at least the next several years and cannot be certain that we will ever achieve profitability. As a result, our business is subject to all of the risks inherent in the development of a new business enterprise, such as the risks that we may be unable to obtain additional capital needed to support the preclinical and clinical expenses of development and commercialization of our products, to develop a market for our products, to successfully transition from a company with a research and development focus to a company capable of commercializing products and to attract and retain qualified management as well as technical and scientific staff.

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

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

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

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

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

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory agencies, Institutional Review Boards or 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;

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- the need to repeat or conduct additional clinical trials as a result of problems such as inconclusive or negative results, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol or an unacceptable study design;
- an insufficient supply of product materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product materials for FDA and foreign regulatory approval;
- an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials; or
- the placement by a regulatory agency of a trial on a clinical hold.

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

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial or development program, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

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. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products and may harm our business.

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

We may be unable to initiate or continue clinical trials for 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 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 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.

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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 products.

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 obtain regulatory approval for our products.

We have no capacity to manufacture clinical or commercial supplies of our products and intend to rely solely on third parties to manufacture clinical and commercial supplies of all of our products.

We do not intend to manufacture our products for our clinical trials or on a commercial scale and intend to rely on third parties to do so. With the exception of our agreements with DSM Pharmaceuticals, Inc., or DSM, for the commercial supply of Omidria and Hospira Worldwide, Inc. for the commercial supply of liquid OMS103, we have not yet entered into any agreement for the commercial supply of any of our products, and can provide no assurance that we will be able to do so on commercially reasonable terms, if at all. Our agreement with DSM for the supply of Omidria has a term extending through December 31, 2015, which term could be terminated early by either party upon the occurrence of certain specified events, including any mandate from a regulatory authority prohibiting manufacture at DSM's relevant facility in the absence of an agreement with DSM to transfer the manufacture of Omidria to an alternative DSM facility. If DSM is unable or unwilling to manufacture Omidria at its planned facility, or if our supply agreement with DSM is terminated, we will have to transfer the Omidria manufacturing process to another facility or manufacturer. The cost of transferring the Omidria manufacturing process to an alternate DSM manufacturing facility or a different manufacturer, or any significant delays in the timely completion of the transfer of the Omidria manufacturing process, could materially harm our business and prospects. Any significant delays in the manufacture of clinical or commercial supplies of our other products could materially harm our business and prospects.

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

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

In addition, we and our contract manufacturers must comply with 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 products 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 product approval, product seizure or recall or withdrawal of product approval. If the safety of any product 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

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obtain or maintain regulatory approval for or successfully commercialize one or more of our products, 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 products to patients in our clinical trials or on a commercial scale would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending on the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must first approve these manufacturers' facilities and processes, which could require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our products.

Ingredients necessary to manufacture our PharmacoSurgery products may not be available on commercially reasonable terms, if at all, which may delay the development and commercialization of our products.

We must purchase from third-party suppliers the active pharmaceutical ingredients necessary for our contract manufacturers to produce our PharmacoSurgery products for our clinical trials and, if approved, for commercial distribution. Suppliers may not sell these ingredients to us at the time we need them or on commercially reasonable terms, if at all. Although we have or intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of active pharmaceutical ingredients for our PharmacoSurgery products, we have not yet entered into agreements for the supply of all such ingredients and we may be unable to secure all such supply agreements or guarantees. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients in a timely manner or in the minimum guaranteed quantities. If we are unable to obtain and then supply these active pharmaceutical ingredients to our contract manufacturers for our clinical trials or for the manufacture of commercial supplies if products, such as Omidria, are approved, potential regulatory approval of our products or, if approved, commercialization of our products, would be delayed, significantly impacting our ability to develop and commercialize our products, which would materially affect our ability to generate revenue from the sale of our products.

We may need licenses for active ingredients from third parties so that we can develop and commercialize some products from some of our current preclinical programs, which could increase our development costs and delay our ability to commercialize products.

Should we decide to use active pharmaceutical ingredients in any of our products that are proprietary to one or more third parties, we would need to obtain licenses to those active ingredients from those third parties. For example, we intend to use proprietary active ingredients that we have exclusively licensed from Daiichi Sankyo Co., Ltd. for our PDE7 program. If we are unable to access rights to these active ingredients prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate products from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these products. 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 products from these programs.

Our agreements with Vulcan and the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or LSDF, include terms that may reduce the purchase price that a third party would be willing to pay for the GPCR program or for us in a change of control, should we elect to proceed with either of such transactions.

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, that 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.

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

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

Our ability to pursue the development and commercialization of 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. The continued maintenance of these agreements requires us to undertake development activities and, if regulatory approval for marketing is obtained, to pay royalties to each of these organizations upon commercialization of a MASP-2 product, such as OMS721. In addition, we are obligated to pay Helion up to $6.6 million upon the achievement of certain events related to a MASP-2 product, such as the initiation of clinical trials, receipt of marketing approval and reaching specified sales milestones. Our ability to continue development and commercialization of 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 products from our MASP-2 and Plasmin programs depends on third-party developers and manufacturers of biologic drug products.

Any product from our MASP-2 or Plasmin programs would be a biologic drug product and we do not have the internal capability to hybridize, clone or manufacture biologics for clinical or commercial use. There are only a limited number of manufacturers of biologic drug products and we cannot be certain that we can enter into supply agreements with them on commercially reasonable terms, if at all. If we are unable to obtain clinical supplies of drug product for one of these programs, clinical trials or the development of any such product 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 products that are suitable for clinical trials or that can be successfully commercialized or generate revenue through partnerships.

Any products from our preclinical programs, including our PDE7, Plasmin and GPCR programs, must successfully complete preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before entering clinical trials. Many pharmaceutical and biological products do not successfully complete preclinical testing and, even if preclinical testing is successfully completed, may fail in clinical trials. In addition, there can be no assurance that positive results from preclinical studies will be predictive of results obtained from subsequent preclinical studies or clinical trials. For example, our studies of PDE7 inhibitors in different animal models of Parkinson's disease, which may or may not be relevant to the mechanism of action of PDE7 inhibitors in humans, have produced varying results. Further, we cannot be certain

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that any of our preclinical product development programs will generate products that are suitable for clinical testing. For example, we have not yet generated any products from our GPCR program. We may discover that there are fewer drugable 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 products that successfully complete preclinical or clinical testing. If we are unable to develop products, potential corporate partners may be unwilling to enter into partnership agreements with us. We also cannot be certain that any products that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

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

Because we have limited resources, we must focus on clinical and preclinical development programs and products that we believe are the most promising. As a result, we may forego or delay the pursuit of opportunities with other products or other indications that later prove to have greater commercial potential and may not be able to progress development programs, including our GPCR program, as rapidly as otherwise possible. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Further, if we do not accurately evaluate the commercial potential or target market for a particular product, we may relinquish valuable rights to that product through collaboration, license or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our products, 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 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 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:

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- 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;
- 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 that are not patentable and which are unlikely to be adequately protected through trade secrets if, for example, a competitor were to develop independently duplicative, similar or alternative technologies or products.

In addition, to the extent we are unable to obtain and maintain patent protection for one of our products or 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 for follow-on indications.

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

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

If we choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party’s activities do not infringe the patents. It may not be feasible to detect and undertake patent enforcement action to stop infringing activity by a number of individual entities, each on a small scale, such as compounding pharmacies.

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

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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 assure you that third-party patents containing claims covering our products, programs, technologies or methods do not exist, have not been filed, or could not be filed or issued.

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

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

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

In March 2014, we borrowed $32.0 million pursuant to the terms of the Oxford/MidCap Loan Agreement. As collateral for this loan, we pledged substantially all of our assets other than intellectual property. The Oxford/MidCap Loan Agreement restricts our ability to incur additional indebtedness, pay dividends, pledge our intellectual property and engage in significant business transactions such as a change of control of Omeros, so long as we owe any amounts to the lenders under the Oxford/MidCap Loan Agreement. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. In addition, if we default under the Oxford/MidCap Loan Agreement, the lenders may have the right to accelerate all of our repayment obligations under the Oxford/MidCap Loan Agreement and to take control of our pledged assets, which include our cash, cash equivalents and short-term investments, potentially requiring us to renegotiate the Oxford/MidCap Loan Agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. An event of default under the Oxford/MidCap Loan Agreement includes the occurrence of any material adverse effect upon our business operations, properties, assets, results of operations or financial condition, taken as a whole with respect to our viability, that would reasonably be expected to result in our inability to repay the loan. If either lender declares all obligations under the Oxford/MidCap Loan Agreement immediately due and payable upon the occurrence of any event that the lender interprets as constituting an event of default as defined under the Oxford/MidCap Loan Agreement, including but not limited to the lender concluding that a material adverse change has occurred as defined under the Oxford/MidCap Loan Agreement, we will be required to repay the loan immediately or to attempt to reverse the declaration through negotiation or litigation. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline. If we raise any additional debt financing, the terms of such debt could further restrict our operating and financial flexibility.

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

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

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

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies other than on the life of Gregory A. Demopulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, could delay the execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

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

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

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

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

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

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

We are required to make an assessment of the effectiveness of our internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Further, our independent registered public accounting firm has been engaged to express an opinion on the effectiveness of our internal control over financial reporting. Section 404 requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting for each fiscal year. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses.

If we are unable to comply with the requirements of Section 404, management may not be able to assess whether our internal control over financial reporting is effective, which may subject us to adverse regulatory consequences and could result in a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we fail to maintain effective controls and procedures, we may be unable to provide the

required financial information in a timely and reliable manner or otherwise comply with the standards applicable to us as a public company. Any failure by us to provide the required financial information in a timely manner could materially and adversely impact our financial condition and the market value of our securities.

Risks Related to Our Industry

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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 market than products or any future products that we may develop. Our competitors also may market a product that proves to be unsafe or ineffective, which may affect the market for our competing product, or future product, regardless of the safety or efficacy of our product. For example, other pharmaceutical companies, many with significantly greater resources than we have, are developing PDE10 inhibitors similar to our product OMS824, and these companies may be further along in development and have the resources to develop their products at a faster rate than we can. For example, in 2012, Pfizer Inc. announced that its PDE10 inhibitor product candidate failed to demonstrate efficacy in a Phase 2 clinical trial evaluating the compound in acute exacerbation of schizophrenia. This and other potential clinical trial failures of PDE10 inhibitor product candidates may negatively reflect on the ability of OMS824 to demonstrate safety and efficacy. In addition, we believe that other companies are attempting to find compounds that functionally interact with orphan GPCRs. If any of these companies are able to achieve this for a given orphan GPCR before we do, we may be unable to establish a commercially valuable intellectual property position around that orphan GPCR. The failure of any product that we may market to effectively compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition and results of operations.

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

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

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

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

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

Any product for which we obtain marketing approval, 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 is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or the approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products or their manufacture, 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.

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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 our products 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. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain and maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the commercialization of our products progresses, or that future claims against us will be covered by our product liability insurance. Although we currently have product liability insurance coverage for our clinical trials, our insurance coverage may not reimburse us or may be insufficient to reimburse us for any or all expenses or losses we may suffer. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage could have a material adverse effect on our business, financial condition and results of operations.
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, 2014, our stock traded as high as $14.69 per share and as low as $3.65 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:

- FDA or EMA actions related to our NDA and MAA submissions for Omidria;
- FDA or foreign regulatory actions related to any of our other products;
- results from our clinical development programs, including the data from our ongoing clinical development programs evaluating Omidria, OMS103, OMS824, OMS721 and PPAR ;
- announcements regarding the progress of our preclinical programs, including without limitation our GPCR program;
- failure of any of our products, if approved, to achieve commercial success;
- quarterly variations in our results of operations or those of our competitors;
- our ability to develop and market new and enhanced 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 our products;
- changes in governmental regulations or in the status of our regulatory approvals;
- changes in earnings estimates or recommendations by securities analysts;
- any major change in our board or management;
- general economic conditions and slow or negative growth of our markets; and
- political instability, natural disasters, war and/or events of terrorism.

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

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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. In addition, the underwriting agreement we entered into in connection with our March 2014 public offering prohibits us from issuing our equity securities, subject to certain exceptions, through June 12, 2014 plus up to an additional 18 days in certain circumstances. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or one or more of our other research and development initiatives. We also could be required to seek collaborators for one or more of our current or future products at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might be available or to relinquish or license on unfavorable terms our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves. We also may have insufficient funds or otherwise be unable to advance our preclinical programs, such as potential new drug targets developed from our GPCR program, to a point where they can generate revenue through partnerships, collaborations or other arrangements. Any of these events could significantly harm our business and prospects and could cause our stock price to decline.

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

Approximately 9.5 million shares of common stock that are either subject to outstanding warrants or subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of shareholders to fill board vacancies and the ability of our board of directors to issue preferred stock without shareholder approval. In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of shareholders owning 10% or more of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

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

Our business requires significant funding, and we have not generated any material revenue. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Additionally, under the Oxford/MidCap Loan Agreement, we have agreed not to pay any dividends so long as we have any outstanding obligations under the 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 your sole source of potential gain in the foreseeable future, and you should not rely on an investment in our common stock for dividend income.

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ITEM 6. EXHIBITS

Exhibit Number	Description
4.1(1)	Notice Regarding the Extension of the Expiration Date to September 29, 2014 of Warrants to Purchase up to an Aggregate of 197,478 Shares of the Common Stock of Omeros Corporation
10.1(2)	Loan and Security Agreement among Omeros Corporation, Oxford Finance LLC and MidCap Financial SBIC, LP dated March 5, 2014
10.2(2)	Form of Secured Promissory Note issued by the registrant to Oxford Finance LLC dated March 5, 2014
10.3(2)	Form of Secured Promissory Note issued by the registrant to MidCap Financial SBIC, LP dated March 5, 2014
10.4(3)	Underwriting Agreement, dated March 14, 2014, among Omeros Corporation and Cowen and Company, LLC, as representative of the Underwriters
10.5††	Pharmaceutical Manufacturing and Supply Agreement dated March 5, 2014 by and between DSM Pharmaceuticals, Inc. and Omeros Corporation
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 from the registrant's Current Report on Form 8-K filed on April 3, 2014 (File No. 001-34475).

(2) Incorporated by reference from the registrant's Current Report on Form 8-K filed on March 7, 2014 (File No. 001-34475).

(3) Incorporated by reference from the registrant's Current Report on Form 8-K filed on March 18, 2014 (File No. 001-34475).

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

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SIGNATURES

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

OMEROS CORPORATION

Dated: May 12, 2014	/s/ Gregory A. Demopulos Gregory A. Demopulos, M.D. President, Chief Executive Officer and Chairman of the Board of Directors
Dated: May 12, 2014	/s/ Michael A. Jacobsen Michael A. Jacobsen Vice President, Finance, Chief Accounting Officer and Treasurer