OMEROS CORP
Form 10-Q
August 09, 2016
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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 June 30, 2016
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 001-34475

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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 August 4, 2016, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 39,293,131.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part II of this Quarterly Report on Form 10-Q under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our other filings with the Securities and Exchange Commission, or SEC. Given these risks, uncertainties and other factors, actual results or anticipated developments may not be realized or, even if substantially realized, may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements, which represent our estimates and

assumptions only as of the date of the filing of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable

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law, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$4,589	$ 1,365
Short-term investments	16,648	26,898
Receivables	8,806	6,517
Inventory	1,780	472
Prepaid expense	2,282	1,894
Total current assets	34,105	37,146
Property and equipment, net	1,251	951
Restricted cash and investments	10,679	10,679
Other assets	73	219
Total assets	$46,108	$ 48,995
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$5,420	$ 6,428
Accrued expenses	10,452	9,752
Current portion of notes payable	193	73
Total current liabilities	16,065	16,253
Notes payable, net	69,833	49,769
Deferred rent	9,205	9,207
Commitments and contingencies (Note 8)		
Shareholders' deficit:		
Preferred stock, par value $0.01 per share, 20,000,000 shares authorized and none issued and outstanding at June 30, 2016 and December 31, 2015		—
Common stock, par value $0.01 per share, 150,000,000 shares authorized at June 30, 2016 and December 31, 2015; 39,277,231 and 38,040,891 issued and outstanding at June 30, 2016 and December 31, 2015, respectively	393	380
Additional paid-in capital	386,905	376,528
Accumulated deficit	(436,293)	(403,142)
Total shareholders' deficit	(48,995)	(26,234)
Total liabilities and shareholders' deficit	$46,108	$ 48,995

See notes to condensed consolidated financial statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenues				
Product sales, net	$10,004	$3,125	$17,250	$3,363
Grant revenue	—	62	173	212
Total revenue	10,004	3,187	17,423	3,575
Costs and expenses				
Cost of product sales	327	365	654	376
Research and development	10,231	10,900	25,665	20,218
Selling, general and administrative	10,375	7,889	21,485	16,878
Total costs and expenses	20,933	19,154	47,804	37,472
Loss from operations	(10,929)	(15,967)	(30,381)	(33,897)
Interest expense	(1,857)	(937)	(3,232)	(1,894)
Other income (expense), net	174	224	462	442
Net loss	$(12,612)	$(16,680)	$(33,151)	$(35,349)
Comprehensive loss	$(12,612)	$(16,680)	$(33,151)	$(35,349)
Basic and diluted net loss per share	$(0.32)	$(0.44)	$(0.86)	$(0.95)
Weighted-average shares used to compute basic and diluted net loss per share	39,178,547	37,846,832	38,747,816	37,165,196

See notes to condensed consolidated financial statements

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

	Six Months Ended June 30,	
	2016	2015
Operating activities:		
Net loss	$(33,151)	$(35,349)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	122	107
Stock-based compensation expense	7,031	4,898
Non-cash interest expense	684	442
Changes in operating assets and liabilities:		
Receivables	(2,289)	(2,679)
Inventory	(1,308)	(65)
Prepaid expenses and other assets	(242)	(228)
Accounts payable and accrued expenses	(268)	(1,229)
Deferred rent	(2)	82
Net cash used in operating activities	(29,423)	(34,021)
Investing activities:		
Purchases and sales of property and equipment	(34)	(114)
Purchases of investments	(20,625)	(79,403)
Proceeds from the sale and maturities of investments	30,875	37,050
Net cash provided by (used in) investing activities	10,216	(42,467)
Financing activities:		
Proceeds from issuance of common stock and pre-funded warrants, net	724	79,076
Proceeds from borrowings under notes payable, net	19,864	—
Payments on notes payable	(34)	(2,342)
Proceeds upon exercise of stock options and warrants	1,877	1,961
Net cash provided by financing activities	22,431	78,695
Net increase in cash and cash equivalents	3,224	2,207
Cash and cash equivalents at beginning of period	1,365	354
Cash and cash equivalents at end of period	$4,589	$2,561
Supplemental cash flow information		
Cash paid for interest	$2,005	$1,471
Issuance of warrants in connection with the Amendment to the Loan Agreement	$758	$—
Property acquired under capital lease	$388	$—
Prepaid expenses not yet paid	$1,035	$68

See notes to condensed consolidated financial statements

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OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

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

Basis of Presentation

Our condensed consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions have been eliminated and we have determined we operate in one segment. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of June 30, 2016 and for the three and six months ended June 30, 2016 and 2015 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2015 has been derived from our audited financial statements but does not include all of the information and footnotes required by GAAP for audited annual financial information.

The accompanying unaudited condensed consolidated financial statements and related notes thereto 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, 2015, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 15, 2016.

Product Sales, Net

We record revenue from OMIDRIA sales when the product is delivered to our wholesalers.

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

Use of Estimates

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

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Liquidity and Capital Resources

As of June 30, 2016, we had $21.2 million in cash, cash equivalents and short-term investments. In addition, we have $10.0 million in restricted cash and investments that must be maintained in depository and investment accounts with East West Bank (EWB) pursuant to the Loan and Security Agreement (the Loan Agreement) entered into in December 2015 with Oxford Finance LLC (Oxford) and EWB as well as $679,000 to secure a letter of credit for the Omeros Building lease. As of June 30, 2016 we have $70.0 million in notes payable which contain financial covenants requiring us to achieve $70.0 million in OMIDRIA net revenues during calendar year 2016 and quarterly OMIDRIA net revenues of $25.0 million in 2017 and $30.0 million in 2018, or maintain 50% of the then-outstanding principal and other obligations under the Loan Agreement in restricted cash and certain eligible term investments. If the OMIDRIA net revenue covenant is met for any quarter of 2017 or 2018, any additional cash collateral requirement then in effect would be removed. If we are unable to meet these financial covenants for any period, obtain a waiver from the lenders or otherwise re-negotiate the Loan Agreement, the lenders could declare all obligations under the Loan Agreement to be due and payable and pursue all other remedies available to the lenders under the Loan Agreement. We expect to continue to incur losses until such time as OMIDRIA product sales, corporate partnerships and/or licensing revenues from products or programs are adequate to support our ongoing operating expenses and debt service, including maintenance of any restricted cash and investments, if required. We are unable to predict if or when this may occur, and until it does occur, we will need to continue to raise additional funds through public or private equity securities sales, including under our At Market Issuance Sales Agreement (the ATM Agreement) with JonesTrading Institutional Services LLC (JonesTrading) (see Note 9 for further detail), through the incurrence of additional debt, through corporate partnerships, through asset sales or through the pursuit of collaborations and licensing arrangements related to certain of our products or programs. These conditions raise a substantial doubt about our ability to continue as a going concern. If we are unable to become cash-flow positive or to raise additional capital as and when needed, or upon acceptable terms, such failure would have a significant negative impact on our financial condition.

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

Recently Adopted Accounting Pronouncements

For the year ended December 31, 2015 we adopted and applied retrospectively Financial Accounting Standards Board (FASB) Accounting Standards Update, or ASU, No. 2015-03, related to simplifying the presentation of debt issuance costs. This standard requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction to the liability.

Recent Accounting Pronouncements

In August 2014, FASB issued ASU No. 2014-15 related to disclosure of an entity’s ability to continue as a going concern. This standard requires management to evaluate whether substantial doubt exists regarding the entity’s ability to continue as a going concern at each reporting period for a duration of one year after the date the financial statements are issued or available to be issued and to provide related footnote disclosures. This standard must be applied prospectively and is effective for interim and annual periods ending after December 15, 2016. We are monitoring for any conditions and events that could raise substantial doubt about our ability to continue as a going concern. The evaluation of the significance of those conditions and events and the related impact upon our disclosures, if applicable, will be disclosed in our annual financial statements for the year ended December 31, 2016.

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

In March 2016, FASB issued ASU 2016-08 related to revenue recognition. This standard is an amendment to ASU 2014-09 relating to revenue from contracts with customers. This amendment clarifies an entity's revenue recognition for a performance obligation based on principal versus agent considerations. This standard has the same effective date and transition requirements as ASU 2014-09, as amended, which requires that the guidance must be applied retroactively to each prior reporting period presented or retrospectively with the cumulative effect of applying the standard recognized in the period adopted. As amended, the standard is effective for interim and annual periods beginning after December 15, 2017 and cannot be adopted before the original effective date, which was for periods beginning after December 15, 2016. We are currently evaluating the impact that this standard may have on our financial statements once it is adopted.

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In March 2016, FASB issued ASU 2016-09 that changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting and for making a policy election to account for forfeitures as they occur rather than on an estimated basis. The guidance is effective for interim and annual periods beginning after December 15, 2016 with early adoption permitted. We are currently evaluating the impact that this standard may have on our financial statements once it is adopted and the timing of adoption.

In April and May 2016, FASB issued ASU 2016-10 and ASU 2016-12, respectively. Both standards are amendments to ASU 2014-09 related to revenue from contracts with customers. ASU 2016-10 clarifies an entity's revenue recognition when identifying performance obligations and licensing. ASU 2016-12 clarifies the objective of the collectibility criterion, one of the five steps of ASU 2014-09. This amendment also establishes practical expedients for sales-tax considerations and contract modifications. Both standards have the same effective date and transition requirements as ASU 2014-09, as amended. We are currently evaluating the impact that these standards may have on our financial statements once they are adopted.

Note 2—Net Loss Per Share

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

The basic and diluted net loss per share amounts for the three and six months ended June 30, 2016 and 2015 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:

	June 30,	
	2016	2015
Outstanding options to purchase common stock	9,501,818	8,427,501
Warrants and pre-funded warrants to purchase common stock	100,602	1,149,249
Total	9,602,420	9,576,750

Note 3—Cash, Cash Equivalents and Investments

As of June 30, 2016 and December 31, 2015, all investments are classified as short-term and available-for-sale on the accompanying Condensed Consolidated Balance Sheets. We did not own any securities with unrealized loss positions as of June 30, 2016 or December 31, 2015. Investment income, which is included as a component of other income (expense), consists of interest earned.

Note 4—Fair-Value Measurements

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

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

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

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

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

	June 30, 2016			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	$10,679	$ —	$ —	$10,679
Money-market funds classified as short-term investments	16,648	—	—	16,648
Total	$27,327	$ —	$ —	$27,327

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

Cash held in demand deposit accounts of $4.6 million and $1.4 million is excluded from our fair-value hierarchy disclosure as of June 30, 2016 and December 31, 2015, respectively. There were no unrealized gains and losses associated with our short-term investments as of June 30, 2016 or December 31, 2015. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets for receivables, accounts payable and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

Note 5—Inventory

The components of inventory are as follows:

	June 30, 2016	December 31, 2015
	(In thousands)	
Raw materials	$101	$ 93
Work-in-process	1,559	158
Finished goods	120	221
Total inventory	$1,780	$ 472

Work-in-process consists of manufactured vials of OMIDRIA which have not been packaged into finished goods.

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Note 6—Accrued Liabilities

Accrued liabilities consisted of the following:

	June 30, 2016	December 31, 2015
	(In thousands)	
Consulting and professional fees	$2,898	$ 2,400
Employee compensation	2,729	2,590
Contract research and development	2,138	2,973
Other accruals	1,448	681
Clinical trials	1,239	1,108
Total accrued liabilities	$10,452	$ 9,752

Note 7—Notes Payable

In December 2015, we entered into the Loan Agreement pursuant to which we borrowed $50.0 million. In May 2016, we entered into the First Amendment to the Loan Agreement (the Amendment) whereby we accelerated the borrowing of the additional $20.0 million potentially available to us under the Loan Agreement. After deducting all loan initiation costs, we received $19.9 million in net proceeds. The Amendment did not modify the interest rate or any terms or covenants of the Loan Agreement except to increase the final payment fee rate applicable to the additional $20.0 million borrowed from 5.25% to 6.25% reflecting the accelerated draw-down of the additional loan. As of June 30, 2016, our outstanding principal balance is $70.0 million and our loan maturity fee is $5.0 million. Interest under the Loan Agreement accrues on the loans at an annual rate of 9.25%. Our monthly interest-only payments of $539,600 are due through July 1, 2017. Beginning August 1, 2017, monthly principal and interest payments of $2.6 million are due through the January 1, 2020 maturity date. In connection with the Amendment, we issued warrants to purchase an aggregate of 100,602 shares of Omeros common stock (the Warrants) to Oxford and EWB at the then current market price of $9.94 per share. We accounted for the Warrants as a discount to our notes payable. See Note 9 for further discussion of the Warrants.

We accounted for the Amendment as a debt modification and, accordingly, the unamortized discount and debt issuance costs associated with the Loan Agreement are being amortized to interest expense using the effective interest method over the remaining term of the Loan Agreement.

The Loan Agreement contains covenants that require us to maintain $10.0 million in restricted cash and certain eligible term investments and limit or restrict our ability to enter into certain transactions. In addition, we are required to either meet an annual OMIDRIA net revenue minimum for 2016 of $70.0 million and quarterly OMIDRIA revenue minimums in 2017 and 2018, or maintain 50% of the then-outstanding note payable balance in restricted cash and certain eligible term investments. The Loan Agreement also includes provisions related to events of default, the occurrence of a material adverse effect and changes of control. The occurrence of an event of default could result in the acceleration of the Loan Agreement and, under certain circumstances, could increase our interest rate by 5.0% per annum during the period of default. There was no event of default under the Loan Agreement as of June 30, 2016.

As of June 30, 2016, the remaining unamortized discount and debt issuance costs associated with the debt were $5.1 million and $440,700, respectively.

Note 8—Commitments and Contingencies

Development Milestones and Product Royalties

We have retained control of worldwide commercial rights to OMIDRIA, to all of our product candidates and to our programs other than OMS103. We may be required, in connection with existing in-licensing or asset acquisition agreements, to make certain royalty and milestone payments and we cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. See Note 9 to our Consolidated Financial Statements for the year ended December 31, 2015 included in our Annual Report on Form 10-K as filed with the SEC on March 15, 2016.

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Contracts

We have various agreements with third parties that collectively require payment of termination fees totaling $1.3 million as of June 30, 2016 if we cancel the work within specific time frames, either prior to commencing or during performance of the contracted services.

Litigation

As described within Note 9 of the “Notes to Consolidated Financial Statements” included in our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on March 15, 2016, we filed a patent infringement lawsuit against Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC (collectively, Par) following our receipt of a Paragraph IV Notice Letter from Par stating that it had filed an Abbreviated New Drug Application (ANDA) seeking approval from the FDA to market a generic version of OMIDRIA before the expiration of three Orange Book-listed patents covering OMIDRIA. In each of April 2016 and August 2016, we amended the lawsuit to assert an additional OMIDRIA patent, both additional patents having been granted by the U.S. Patent and Trademark Office after Par sent its original Paragraph IV Notice Letter. In May 2016, Par stipulated to infringement of the first four asserted patents, and the court entered a partial judgment that Par’s filing of its ANDA constitutes an act of infringement of the claims of the first four asserted patents. Par maintains defenses and counterclaims alleging that the claims of the patents are invalid. The filing of our suit against Par triggered a stay of the FDA’s final approval of Par’s ANDA, which is expected to remain in effect until January 2018. We continue to believe that the assertions in Par’s Paragraph IV Notice Letter and its defenses and counterclaims asserted in the litigation that the asserted patent claims are allegedly invalid do not have merit, and we intend to defend our patents vigorously in the litigation against Par.

Note 9—Shareholders’ Equity

Common Stock

At Market Issuance Sales Agreement - In January 2016, we entered into the ATM Agreement with JonesTrading pursuant to which we may direct JonesTrading to sell shares of our common stock with an aggregate offering price of up to $100.0 million directly on The Nasdaq Global Market, through a market maker other than on an exchange or in negotiated transactions. Any sales made under the ATM Agreement are based solely on our instructions and JonesTrading will receive a 1.7% commission from the gross proceeds. The ATM Agreement may be terminated by either party at any time upon 10 days' notice to the other party or by JonesTrading at any time in certain circumstances including the occurrence of a material adverse effect to Omeros. During the three and six months ended June 30, 2016, we sold 64,565 shares of our common stock at an average price of $11.41 per share under the ATM Agreement and received net proceeds of $724,000.

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

For the six months ended June 30, 2016, we received proceeds of $1.9 million upon the exercise of stock options and pre-funded warrants which resulted in the issuance of 1,171,775 shares of common stock.

Warrants

In connection with the Amendment on May 18, 2016, we issued the Warrants to purchase an aggregate of 100,602 shares of our common stock to Oxford and EWB. We evaluated the terms of the Warrants and determined that the Warrants should be recorded as permanent equity. The aggregate fair value of the Warrants on the issue date was $758,000, which we recorded as a discount to our notes payable. We are amortizing the Warrants over the remaining term of the Loan Agreement using the effective interest method. The Warrants are exercisable through May 18, 2023 at an exercise price per share of $9.94 per share.

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Note 10—Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Research and development	$1,219	$1,229	$3,374	$2,554
Selling, general and administrative	1,391	1,151	3,657	2,344
Total	$2,610	$2,380	$7,031	$4,898

In February 2016, in connection with our annual employee review process, we granted qualified employees options to purchase approximately 1.3 million shares of our common stock with an exercise price of $10.27.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Estimated weighted-average fair value	$8.50	$12.63	$6.93	$12.97
Weighted-average assumptions				
Expected volatility	74 %	69 %	74 %	70 %
Expected term, in years	5.8	5.9	5.7	5.9
Risk-free interest rate	1.37 %	1.71 %	1.40 %	1.61 %
Expected dividend yield	— %	— %	— %	— %

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, 2015	8,310,235	$ 7.97		
Granted	1,663,155	10.84		
Exercised	(422,525)	4.42		
Forfeited	(49,047)	14.02		
Balance at June 30, 2016	9,501,818	$ 8.60	6.44	$ 23,678
Vested and expected to vest at June 30, 2016	9,225,654	$ 8.51	6.36	$ 23,615
Exercisable at June 30, 2016	6,764,948	$ 7.41	5.45	$ 23,051

At June 30, 2016, excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with our unvested options is $16.6 million, and 1,896,593 shares were available to grant.

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

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

Overview

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

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

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

Products, Product Candidates, Development Programs and Platforms

OMIDRIA. OMIDRIA is approved in the U.S. by the FDA for use during cataract surgery or IOL replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain, and is approved in all European Union, or EU, member states plus Iceland, Lichtenstein and Norway for use during cataract surgery and other IOL replacement procedures to maintain mydriasis (pupil dilation), to prevent miosis (pupil constriction) and to reduce postoperative eye pain. We broadly launched OMIDRIA in the U.S. in April 2015 primarily through wholesalers which, in turn, sell to ambulatory surgery centers, or ASCs, and hospitals. The Centers for Medicare and Medicaid Services, or CMS, has granted transitional pass-through reimbursement status for OMIDRIA, which we expect to run until January 1, 2018. Pass-through status allows for separate payment (i.e., outside the bundled payment) under Medicare Part B for new drugs and other medical technologies that meet well-established criteria specified by federal regulations governing Medicare spending. In the event that pass-through reimbursement status is not extended or separate reimbursement is not obtained for OMIDRIA on or before January 1, 2018, the per unit price we receive for OMIDRIA may be adversely affected.

In May 2016, we entered into an exclusive supply and distribution agreement with ITROM Trading Drug Store, or ITROM, for the sale of OMIDRIA in the Kingdom of Saudi Arabia, the United Arab Emirates and certain other countries in the Middle East. Within the licensed territory, ITROM is responsible for obtaining marketing authorizations for OMIDRIA, on our behalf, and for promoting, marketing, selling and distributing product supplied by us. We expect ITROM will begin selling OMIDRIA later this year on a limited basis, assuming local submission of appropriate regulatory applications.

In June 2016, we announced the completion of enrollment in an FDA required post-marketing OMIDRIA pediatric clinical trial, which, if completed in compliance with FDA clinical trial regulations and pre-specified timelines, will result in eligibility for an additional six months of marketing exclusivity for OMIDRIA. The trial enrolled patients 0-3 years of age undergoing cataract surgery. Consistent with FDA's request, over 70 patients were enrolled and treated. OMIDRIA is not yet approved for use in patients less than 18 years of age, and the trial is expected to provide clinical information on the use of OMIDRIA in the pediatric population.

OMS103. OMS103, part of our PharmacoSurgery platform, was developed for use during all arthroscopic procedures, including knee and shoulder arthroscopy, and completed Phase 3 trials in patients undergoing arthroscopic anterior

cruciate ligament reconstruction and arthroscopic partial meniscectomy. In June 2015, we entered into an exclusive licensing agreement, or the OMS103 Agreement, with Fagron Compounding Services, LLC, d/b/a Fagron Sterile Services, and JCB Laboratories, LLC, or collectively Fagron, an FDA-registered human drug outsourcing facility, under which Fagron is obligated to produce under Good Manufacturing Practices, or GMP, and to commercialize OMS103 in the U.S. Fagron has not performed its performance diligence obligations under the OMS103 Agreement, including initiating sales, and we are evaluating our options regarding the OMS103 Agreement and our OMS103 program.

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

- MASP-2 - OMS721. OMS721, our lead mannan-binding lectin-associated serine protease-2, or MASP-2, antibody, is being developed for diseases of the lectin pathway, one of the principal complement activation pathways, which is believed to contribute to significant tissue injury and pathology. One group of such diseases is thrombotic microangiopathies, or TMAs, including atypical hemolytic uremic syndrome, or aHUS, thrombotic thrombocytopenic purpura, or TTP, and hematopoietic stem-cell transplant, or HSCT, -related TMA. We have a Phase 3 clinical program consisting of one single-arm (i.e., no control arm), open-label trial evaluating OMS721 in patients with newly diagnosed or ongoing aHUS and initiation of enrollment in this trial is planned for later this year. In July 2016, we announced that we received advice from the European Medicines Agency allowing us to use data from this single Phase 3 trial to also support a marketing approval application in the EU. We are also currently conducting two Phase 2 clinical programs, one in patients with TMAs (i.e., HSCT-related TMA and TTP) as well as a second Phase 2 clinical program in patients with corticosteroid-dependent renal diseases, including immunoglobulin A, or IgA, nephropathy, membranous nephropathy, lupus nephritis and C3 glomerulopathy. Patient dosing in the Phase 2 renal disease clinical trial was initiated in April 2016.
- PDE10 - OMS824 for Huntington's disease and Schizophrenia. OMS824, our lead phosphodiesterase 10, or PDE10, inhibitor, is in a Phase 2 clinical program for the treatment of Huntington's disease, in which clinical trials are currently subject to dosing limitations, and a Phase 2 clinical program for schizophrenia, in which no clinical trials are currently active. The dosing limitations in our Phase 2 clinical trial in Huntington's may potentially be removed pending generation, submission and FDA review of additional information. We are conducting nonclinical studies to generate additional data for further discussion with the FDA regarding the dosing limitations and are currently preparing for a re-designed Phase 2 clinical trial in patients with Huntington's disease. As we announced in October 2014, clinical trials evaluating OMS824 in schizophrenia are suspended currently at the request of the FDA. Given that there was no active schizophrenia trial at the time of program suspension, the FDA will address the OMS824 schizophrenia program when we have a related trial protocol ready for initiation.
- PPAR - OMS405. In our peroxisome proliferator-activated receptor gamma, or PPAR , program, Phase 2 clinical trials have been conducted by our collaborators to evaluate a PPAR agonist, alone or in combination with other agents, for treatment of addiction to opioids and to nicotine. Our collaborators are analyzing data from these trials and expect to present relevant information in manuscripts to be published at a later date.
- OMS201-Urology. OMS201, our PharmacoSurgery product candidate for use during urological procedures, including uroendoscopic procedures, completed a Phase 1/Phase 2 clinical trial in 2010 and is not currently in active clinical trials.

Development Programs and Platforms. Our preclinical programs and platforms include:

- PDE7 - OMS527. In our PDE7 program, we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders.
- Plasmin - OMS616. In our Plasmin program, we are advancing novel antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma as well as for other hyperfibrinolytic states (e.g., liver disease).
- MASP-3 - OMS906. In our mannan-binding lectin-associated serine protease-3, or MASP-3 program, we are developing MASP-3 inhibitors for the treatment of disorders related to the alternative pathway of the complement system. In August 2016, we announced results from our OMS906 complement program showing that OMS906 inhibited activation of the alternative pathway of complement and reduced both the incidence and severity of disease in a well-established animal model of arthritis. We are initiating the process of manufacturing scale-up of OMS906 in preparation for clinical trials.
- GPCR Platform and Programs. We have developed a proprietary cellular redistribution assay, or CRA, which we use in a high-throughput manner to identify synthetic ligands, including antagonists, agonists and inverse agonists, that bind to and affect the function of orphan GPCRs. We are conducting in vivo preclinical efficacy studies and optimizing compounds for a number of targets including: GPR17, linked to myelin formation; GPR101, linked to appetite and eating disorders; GPR151, linked to schizophrenia and cognition; GPR161, which is associated with

triple negative breast cancer; GPR183, linked to osteoporosis and to Epstein-Barr virus infections and related diseases; and GPR174, which appears to be involved in the modulation of regulatory T cells, or “T-regs,” known to be important in autoimmune disease, such as multiple sclerosis, and in cancer and organ transplantation.

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- Antibody Platform. Our proprietary ex vivo platform for the discovery of novel, high-affinity monoclonal antibodies, which was in-licensed from the University of Washington and then further developed by our scientists, utilizes a chicken B-cell lymphoma cell line. We have generated antibodies to several clinically significant targets, including highly potent antibodies against MASP-3, and our platform continues to add to our pipeline antibodies against additional important targets.

Financial Summary

We recognized net losses of $12.6 million and $16.7 million for the three months ended June 30, 2016 and 2015, respectively, and $33.2 million and $35.3 million for the six months ended June 30, 2016 and 2015, respectively. As of June 30, 2016, our accumulated deficit was $436.3 million, total shareholders' deficit was $49.0 million and we had $21.2 million in cash, cash equivalents and short-term investments available for general corporate use. In addition, we had restricted cash and investments of $10.7 million that we are required to maintain in depository and investment accounts pursuant to (a) our Loan and Security Agreement, or the Loan Agreement, with Oxford Finance LLC, or Oxford, and East West Bank, or EWB, and (b) our lease related to the Omeros Building.

Results of Operations

Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Product sales, net	$10,004	$3,125	$17,250	$3,363
Small Business Innovative Research Grants (SBIR)	—	62	173	212
Total revenue	$10,004	$3,187	$17,423	$3,575

The increase in product sales, net during the three and six months ended June 30, 2016 compared to the same periods in 2015 was due to continued acceptance of and increased demand for OMIDRIA in the ophthalmic surgery community. During the quarter ended June 30, 2016, our OMIDRIA reported revenue increased $2.8 million, or 38%, from the prior quarter.

We expect product sales, net will continue to expand as OMIDRIA gains additional market acceptance and existing customers continue to broaden their use of OMIDRIA.

Gross-to-Net Deductions

We record OMIDRIA product sales net of estimated chargebacks, rebates, distribution fees and product returns. These deductions are generally referred to as gross-to-net deductions. A summary of our gross-to-net accrual for the six months ended June 30, 2016 is as follows:

	Chargebacks and Rebates	Distribution Fees and Product Return Allowances	Total
	(In thousands)		
Balance as of December 31, 2015	$180	$ 277	$457
Provision related to current period sales	854	580	1,434
Payments made/credits granted	(679)	(389)	(1,068)
Balance as of June 30, 2016	$355	$ 468	$823

Chargebacks and Rebates. We have entered into a variety of agreements including a Pharmaceutical Pricing Agreement, a Federal Supply Schedule agreement, a 340B prime vendor agreement and a Medicaid Drug Rebate Agreement which allow eligible entities to receive discounts on their qualified purchases of OMIDRIA. We record a

provision for estimated chargebacks and rebates related to these agreements at the time of sale and reduce the accrual when payments are made or credits are granted.

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In October 2015, we launched the OMIDRIAssure Reimbursement Services Program to expand patient access to OMIDRIA. We record a provision for estimated OMIDRIAssure claims at the time of sale and reduce the accrual when payments are made.

We expect future chargeback and rebate deductions as a percentage of gross OMIDRIA product sales to increase based on our 340B prime vendor agreement, the increased use of OMIDRIAssure and increased volume of purchases eligible for government-mandated discounts such as 340B, and rebates.

Distribution Fees and Product Return Allowances. We pay our wholesalers a distribution fee for services they perform for us based on the dollar value of their purchases of OMIDRIA. We record a provision for these charges at the time of sale to the wholesaler and make payments to our wholesalers based on contractual terms.

We allow for the return of product up to 12 months past its expiration date or for product that is damaged or not used by our customers. We record a provision for returns upon sale of OMIDRIA to our wholesaler. When a return or claim is received, we issue a credit memo to the wholesaler against its outstanding receivable to us or reimburse the customer.

We expect distribution fees and product return allowances to generally correlate with changes in product sales.

Research and Development Expenses

Our research and development expenses can be divided into three categories: direct external expenses, which include clinical research and development and preclinical research and development activities; internal, overhead and other expenses; and stock-based compensation expense. Direct external expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations, contract research organizations, or CROs, clinical trial sites, collaborators, licensors and consultants and lab supplies. Costs are reported in preclinical research and development until the program enters the clinic. Internal, overhead and other expenses consist of personnel costs, overhead costs such as rent, utilities and depreciation and other miscellaneous costs. We do not generally allocate our internal resources, employees and infrastructure to any individual research project because we deploy them across multiple clinical and preclinical projects that we are advancing in parallel.

The following table illustrates our expenses associated with these activities:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Direct external expenses:				
Clinical research and development:				
OMS721	$2,701	$3,152	$8,697	$4,394
OMIDRIA (OMS302)	684	974	1,949	1,727
OMS824	53	518	325	1,051
Other clinical programs	15	10	29	18
Total clinical research and development	3,453	4,654	11,000	7,190
Preclinical research and development	485	327	975	829
Total direct external expenses	3,938	4,981	11,975	8,019
Internal, overhead and other expenses	5,074	4,690	10,316	9,645
Stock-based compensation expense	1,219	1,229	3,374	2,554
Total research and development expenses	$10,231	$10,900	$25,665	$20,218

The decrease in total clinical research and development expenses during the three months ended June 30, 2016 compared to the same period in 2015 is due primarily to lower clinical research and development costs in our OMS824 program due to reduced clinical trial and nonclinical costs, lower clinical manufacturing and clinical trial costs for our OMS721 program and decreased clinical trial costs associated with the completion of enrollment in a post-marketing OMIDRIA pediatric trial. This decrease was partially offset by an increase in total internal, overhead

and other research and development expenses due primarily to increased employee costs.

The increase in total clinical research and development expenses during the six months ended June 30, 2016 compared to the same period in 2015 is due primarily to increased costs for our OMS721 program in connection with clinical manufacturing, clinical trial costs and other clinical research and development activities. This increase was offset by lower

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clinical research and development costs related to our OMS824 program due to reduced clinical trial and nonclinical costs. The increase in total internal, overhead and other expenses during the six months ended June 30, 2016 compared to the same period in 2015 is due primarily to increased employee costs.

In addition, stock-based compensation expenses increased during the six months ended June 30, 2016 compared to the same period in 2015 related to annual company-wide option grants approved in February 2016 with April 1, 2015 vesting commencement dates.

We anticipate that total research and development costs will increase during the remainder of this year due to planned clinical manufacturing and clinical study activities relating primarily to OMS721, subject to increases in OMIDRIA product sales and raising of additional funds to support our planned development activities.

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

We are required to expend substantial resources in the development of our product candidates due to the lengthy process of completing clinical trials and seeking regulatory approval. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could delay our generation of product revenue and increase our research and development expenses and, in turn, have a material adverse effect on our operations, financial condition and liquidity.

Because of the factors above, we are not able to estimate with any certainty when or if we would recognize any net cash inflows from our research and development projects.

Selling, General and Administrative Expenses

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Selling, general and administrative expenses, excluding stock-based compensation expense	$8,984	$6,738	$17,828	$14,534
Stock-based compensation expense	1,391	1,151	3,657	2,344
Total selling, general and administrative expenses	$10,375	$7,889	$21,485	$16,878

The increase in selling, general and administrative expenses during the three and six months ended June 30, 2016 compared to the same periods in 2015 was primarily due to increased legal costs associated with the Par lawsuit, increased selling related activities and increased administrative and employee costs. The increase in stock-based compensation expense during the six months ended June 30, 2016 compared to the same period in the prior year was due to annual company-wide option grants approved in February 2016 with April 1, 2015 vesting commencement dates.

We anticipate selling, general and administrative costs will increase during the remainder of this year primarily due to legal costs in connection with enforcing our patents and pursuing our patent infringement claims related to Par's effort to obtain FDA approval for a generic version of OMIDRIA and incremental sales and marketing programs.

Interest Expense

Three Months	Six Months Ended

	Ended June 30,			
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Interest expense	$1,857	$937	$3,232	$1,894

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The increase in interest expense during the three and six months ended June 30, 2016 compared to the same periods in the prior year was due to the increase in our outstanding notes payable balance during the comparative periods. Interest expense is expected to be approximately $700,000 per month due to the incremental $20.0 million we borrowed under the Loan Agreement in May 2016.

Other Income (Expense), Net

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)		(In thousands)	
Other income (expense), net	$174	$224	$462	$442

Other income (expense), net principally includes sublease rental income and interest earned. The decrease during the three months ended June 30, 2016 compared to the same period in the prior year was due to a sublease expiring in February 2016.

Financial Condition - Liquidity and Capital Resources

As of June 30, 2016, we had $21.2 million in cash, cash equivalents and short-term investments available for general corporate use that are held principally in interest-bearing instruments, including money-market accounts. In addition, we have restricted cash and investments of $10.7 million that are maintained in depository and investment accounts pursuant to (a) our Loan Agreement, and (b) our lease related to the Omeros Building. Cash in excess of our immediate requirements is invested in accordance with our established guidelines that are intended to preserve principal and maintain liquidity.

Future Funding Requirements

We have experienced net losses and negative cash flow from operations since inception, and as of June 30, 2016, had an accumulated deficit of $436.3 million, and we expect to continue to incur losses until such time as OMIDRIA product sales, corporate partnerships and/or licensing revenues from products or programs are adequate to support our ongoing operating expenses and debt service. As of June 30, 2016 we had unrestricted cash, cash equivalents and short-term investments of $21.2 million. As of June 30, 2016 we had $70.0 million in notes payable which contain financial covenants requiring us to achieve $70.0 million in OMIDRIA net revenues during calendar year 2016 and quarterly OMIDRIA net revenues of $25.0 million in 2017 and $30.0 million in 2018, or maintain 50% of the then-outstanding principal and other obligations under the Loan Agreement in restricted cash and certain eligible term investments. If the OMIDRIA net revenue covenant is met for any quarter of 2017 or 2018, any additional cash collateral requirement then in effect would be removed. If we are unable to meet these financial covenants for any period, obtain a waiver from the lenders or otherwise re-negotiate the Loan Agreement, the lenders could declare all obligations under the Loan Agreement to be due and payable and pursue all other remedies available to the lenders under the Loan Agreement. To meet our projected funding requirements through June 30, 2017, we expect to use cash on hand, future OMIDRIA revenues and additional funds we intend to raise through corporate partnerships, through the incurrence of additional debt, through asset sales, through the pursuit of collaborations and licensing arrangements related to certain of our products or programs or through public or private equity securities sales, including our At Market Issuance Sales Agreement, or the ATM Agreement, with JonesTrading Institutional Services LLC, or JonesTrading. These conditions raise a substantial doubt about our ability to continue as a going concern. If we are unable to raise additional capital when needed through one or more of the avenues previously listed, or upon acceptable terms, such failure would have a significant negative impact on our financial condition. Should it be necessary to manage our operating expenses, we would reduce our projected cash requirements through reduction of our expenses by delaying clinical trials, reducing selected research and development efforts, or implementing other

restructuring activities.

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

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Cash Flow Data

	Six Months Ended June 30,	
	2016	2015
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	$(29,423)	$(34,021)
Investing activities	10,216	(42,467)
Financing activities	22,431	78,695

Operating Activities. Net cash used in operating activities was $29.4 million for the six months ended June 30, 2016. The cash used in operating activities was affected by our net loss of $33.2 million, a $2.3 million increase in accounts receivable and a $1.3 million increase in inventory, partially offset by non-cash stock-based compensation expense of $7.0 million. The increase in inventory relates to an accumulation of OMIDRIA inventory to ensure adequate commercial supply of OMIDRIA until such time as additional inventory is expected to become available from our new manufacturer beginning in 2017. The increase in stock-based compensation expense primarily relates to annual company-wide stock option grants approved in February 2016 with April 1, 2015 vesting commencement dates.

Net cash used in operating activities was $34.0 million for the six months ended June 30, 2015. The cash used in operating activities was affected by a net loss of $35.3 million, a $2.7 million increase in accounts receivable and a decrease of $1.2 million in accounts payable and accrued expenses, partially offset by stock-based compensation expense of $4.9 million. The increase in accounts receivable is related to increased sales of OMIDRIA and the decrease in accounts payable and accrued expenses relates to the timing of operating activities and related payments.

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

Net cash provided by investing activities in the six months ended June 30, 2016 was $10.2 million, an increase of $52.7 million from 2015. The six months ended June 30, 2016 was affected by $30.9 million sales of short-term investments partially offset by the purchase of short-term investments of $20.6 million compared to the same period in the prior year, during which we purchased short-term investments of $79.4 million and sold $37.1 million of short-term investments in order to provide cash for operating activities.

Financing Activities. Net cash provided by financing activities in the six months ended June 30, 2016 was $22.4 million, a decrease of $56.3 million compared to the same period in 2015. Net cash provided by financing activities for the six months ended June 30, 2016 was due to proceeds from the borrowings of the additional $20.0 million available to us under the Loan Agreement, $1.9 million from the exercise of options and pre-funded warrants and approximately $724,000 of net proceeds from the issuance of 64,565 shares of our common stock at an average price of $11.41 per share under the ATM Agreement. This compares to the same period in 2015 in which cash provided by financing activities was primarily due to the $79.1 million of net proceeds received from the sale of 3.4 million shares of common stock and pre-funded warrants to purchase 749,250 shares of common stock in our public offering in February 2015 and $2.0 million from proceeds from the exercise of stock options and warrants. The six months ended June 30, 2015 also included $2.3 million of payments on notes payable.

Contractual Obligations and Commitments

Our future minimum contractual commitments and obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2015 that was filed with the SEC on March 15, 2016. Other than the following, our future minimum contractual obligations and commitments have not changed materially from the amounts previously reported.

Notes Payable

We initially borrowed $50.0 million under the Loan Agreement in December 2015, and in May 2016 we entered into the First Amendment to the Loan Agreement, or the Amendment, whereby we accelerated the borrowing of the additional $20.0 million potentially available to us under the Loan Agreement. The Amendment did not modify the interest rate or any terms or

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covenants of the Loan Agreement except to increase the final payment fee rate applicable to the additional $20.0 million borrowed from 5.25% to 6.25%, reflecting the accelerated draw-down of the additional loan. Interest under the Loan Agreement accrues on the loans at an annual rate of 9.25%. Our monthly interest-only payments of $539,600 are due through July 1, 2017. Beginning August 1, 2017, monthly principal and interest payments of $2.6 million are due through the January 1, 2020 maturity date. In connection with the Amendment, we issued warrants to purchase an aggregate of 100,602 shares of Omeros common stock to Oxford and EWB at the then current market price of $9.94 per share. See Note 7 to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 15, 2016, for a description of the Loan Agreement terms. There was no event of default under the Loan Agreement as of June 30, 2016.

Goods & Services

We have entered into an agreement with Hospira Worldwide, Inc., or Hospira, for the ongoing commercial supply of OMIDRIA and we are currently completing the manufacturing process transfer, process validation and approval of Hospira as a manufacturing site for OMIDRIA. We anticipate Hospira will be able to provide OMIDRIA commercial product to us beginning in 2017. We have no firm purchase commitments outstanding under this agreement as of June 30, 2016.

We may also be required, in connection with our existing in-licensing or asset acquisition agreements, to make certain royalty and milestone payments and we cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. See Note 9 to our Consolidated Financial Statements for the year ended December 31, 2015 included in our Annual Report on Form 10-K, as filed with the SEC on March 15, 2016, for a description of the agreements that include these royalty and milestone payment obligations.

Critical Accounting Policies and Significant Judgments and Estimates

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

We believe the judgments, estimates and assumptions associated with the following critical accounting policies have the greatest potential impact on our consolidated financial statements:

•Revenue recognition;
•Research and development expenses; and
•Stock-based compensation.

For a detailed discussion of these critical accounting policies and significant judgments and estimates, refer to “Critical Accounting Policies and Significant Judgments and Estimates” within “Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2015 that was filed with the SEC on March 15, 2016. There have not been any material changes in our critical accounting policies and significant judgments and estimates as disclosed in our Annual Report Form 10-K for the year ended December 31, 2015.

Off-Balance Sheet Arrangements

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

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is primarily confined to our investment securities and notes payable. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities. As of June 30, 2016, we had cash, cash equivalents and short-term investments of $21.2 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 material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates and, with our current portfolio of short term investments, we are not exposed to potential loss due to changes in interest rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of June 30, 2016. 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 June 30, 2016, 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 1. LEGAL PROCEEDINGS

In July 2015, we received a Notice Letter from Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC, or collectively, Par, that Par filed an Abbreviated New Drug Application, or ANDA, containing a Paragraph IV Certification under the Hatch-Waxman Act and seeking approval from the FDA to market a generic version of OMIDRIA prior to the expiration of three Omeros patents, U.S. Patent Nos. 8,173,707, 8,586,633 and 9,066,856, which relate to OMIDRIA and that are listed in the FDA's Orange Book for OMIDRIA. These patents were granted following review by the U.S. Patent and Trademark Office, or USPTO, are presumed to be valid under governing law, and can only be invalidated in federal court with clear and convincing evidence. Following receipt of the Paragraph IV Notice Letter we filed a patent infringement lawsuit against Par in the U.S. District Court for the District of New Jersey on September 2, 2015 and a patent infringement lawsuit against Par in the U.S. District Court for the District of Delaware on September 3, 2015. The lawsuits were filed under the Hatch-Waxman Act alleging Par's infringement of U.S. Patent Nos. 8,173,707, 8,586,633 and 9,066,856. Based on our decision to pursue the action in federal court in Delaware, we voluntarily dismissed the complaint filed in the U.S. District Court for the District of New Jersey. The complaint that we filed in the U.S. District Court for the District of Delaware has been served on Par and Par has filed an answer asserting defenses and counterclaims for declaratory judgment of patent invalidity and non-infringement. In April 2016 and August 2016, we amended the complaint to also assert infringement of U.S. Patent Nos. 9,278,101 and 9,399,040, respectively, which issued in March 2016 and July 2016, respectively, and were listed in the Orange Book after Par's Paragraph IV Notice Letter. Par has filed an answer to our amended complaint filed in April 2016 asserting defenses and counterclaims for declaratory judgment of patent invalidity and non-infringement. In May 2016, Par stipulated to infringement of the first four asserted patents and the court endorsed an order entering partial judgment that the filing of Par's ANDA constitutes an act of infringement of the first four above-referenced patents, subject to Par's continued invalidity defenses and any challenge to enforceability. We have reviewed the invalidity assertions in Par's Paragraph IV Notice Letter and defenses and counterclaims and believe they do not have merit, and we intend to defend our patents vigorously in the litigation against Par. Under the Hatch-Waxman Act, we were permitted to file suit within 45 days from receipt of Par's Notice Letter and thereby trigger a 30-month stay of the FDA's final approval of Par's ANDA while the lawsuit against Par is pending. Our lawsuit against Par triggered such a stay, which is expected to remain in effect until late January 2018.

ITEM 1A. RISK FACTORS

The risks and uncertainties described below may have a material adverse effect on our business, prospects, financial condition or operating results. In addition, we may be adversely affected by risks that we currently deem immaterial or by other risks that are not currently known to us. You should carefully consider these risks before making an investment decision. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2015.

Risks Related to Our Products, Programs and Operations

Our ability to achieve profitability is dependent on the commercial success of OMIDRIA. To the extent OMIDRIA is not successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

OMIDRIA is our only product that has been approved by the FDA for commercial sale in the U.S. For the three months ended June 30, 2016, we recorded net sales of OMIDRIA of $10.0 million. We have not generated revenue from sales of OMIDRIA to date that are sufficient to fund fully our operations and cannot provide assurance that we will generate sufficient revenue from OMIDRIA in the future to fund fully our operations. We will need to generate substantially more product revenue from OMIDRIA to achieve and sustain profitability. Our ability to generate significant revenue from OMIDRIA product sales depends on our ability to achieve increased market acceptance of, and to otherwise market and sell effectively, OMIDRIA, which may not occur for a number of reasons, including:

- a lack of acceptance by physicians, patients, government and private payers and other members of the medical community;
- our limited experience in marketing, selling and distributing OMIDRIA or any other product;
- our limited experience managing third-party commercial manufacturing of OMIDRIA or any other product as well as our limited experience managing and maintaining a commercial sales organization;

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- pricing, reimbursement and coverage policies of government and private payers such as Medicare, Medicaid, the Department of Veterans Affairs, or VA, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- the availability, relative price and efficacy of the product as compared to alternative treatment options or branded, compounded or generic competing products;
- an unknown safety risk;
- the failure to enter into and maintain acceptable partnering arrangements for marketing and distribution of OMIDRIA outside of the U.S.;
- changed or increased regulatory restrictions in the U.S., EU and other foreign territories; and
- a lack of adequate financial or other resources.

Our operating results are unpredictable and may fluctuate.

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

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

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

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

Our operations have consumed substantial amounts of cash since our incorporation and, as of June 30, 2016, we had an accumulated deficit of approximately $436.3 million. We expect to continue to spend substantial amounts to:

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

We expect to continue to incur additional losses until such time as we generate significant revenue from the sale of OMIDRIA, other commercial products and/or significant partnering revenues. We are unable to predict the extent of any future losses and cannot provide assurance that we will generate sufficient revenue from OMIDRIA in the future to fund fully our operations. To date we have not generated revenue from sales of OMIDRIA that is sufficient to fund fully our operations. If we are unable to generate sufficient revenue from the sale of OMIDRIA, other commercialized products and/or partnering arrangements, we may never become and remain profitable and will be required to raise additional capital to continue to fund our operations. We cannot be certain that additional capital will be available to us on acceptable terms, if at all, when required. Adverse developments to our financial condition or business, as well as disruptions in the global equity and credit markets, may limit our ability to access capital. If we do not raise additional capital when needed through one or more funding avenues, such as corporate partnering or debt or equity financings, we may have to significantly delay, scale back or discontinue the development or commercialization of

one or more of our product candidates or one or more of our preclinical programs or other research and development initiatives. In addition, we may be required to seek collaborators for one or more of our current or future products at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might

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be available or to relinquish or license on unfavorable terms our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves. We also may have insufficient funds or otherwise be unable to advance our preclinical programs, such as potential new drug targets developed from our GPCR program, to a point where they can generate revenue through partnerships, collaborations or other arrangements. Any of these actions could limit the amount of revenue we are able to generate and harm our business and prospects.

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

Our financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. However, our independent registered public accounting firm has included in its audit opinion for the year ended December 31, 2015 a statement that there is substantial doubt as to our ability to continue as a going concern as a result of our recurring losses and financial condition on December 31, 2015. Our ability to continue as a going concern will require us to generate positive cash flow from operations, obtain additional financing, enter into strategic alliances and/or sell assets. The reaction of investors to the inclusion of a going concern statement by our auditors, our current lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into strategic alliances and/or make our scheduled debt payments on a timely basis or at all. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

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

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

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

we may not be able to maintain or obtain adequate reimbursement for OMIDRIA. In the event that pass-through reimbursement status is not extended or separate reimbursement obtained for OMIDRIA after that date, we expect that OMIDRIA will be included as part of the packaged payment and as a result the per unit price we receive for OMIDRIA would be reduced.

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

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

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

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

Both before and after approval of any product, we and our suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the U.S. and other countries, covering, among other things, testing, manufacturing, quality control, clinical trials, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions: warning letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties; adverse publicity; and disruptions to our business. Further, government investigations into potential violations of these laws would require us to expend considerable resources and face adverse publicity and the potential disruption of our business even if we are ultimately found not to have committed a violation.

Obtaining FDA approval of our product candidates requires substantial time, effort and financial resources and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on any of our product candidates on a timely basis, if at all. Even if we discuss with, and obtain feedback from, the FDA regarding our proposed clinical trials and nonclinical studies before initiating those trials or studies, the FDA may decide that our resulting data are insufficient for approval of our product candidates and require additional preclinical, clinical or other studies or additional work related to chemistry, manufacturing and controls. In addition, we, the FDA or an independent Institutional Review Board or Ethics Committee may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are or would be exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials. If we are required to conduct additional trials or to conduct other testing of our product candidates beyond that which we currently contemplate for regulatory approval, if we are unable to complete successfully our clinical trials or other testing, or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may face substantial additional expenses, be delayed in obtaining marketing approval for our product candidates or may never obtain marketing approval.

We are also required to comply with extensive governmental regulatory requirements after a product has received marketing authorization. Governing regulatory authorities may require post-marketing studies that may negatively impact the commercial viability of a product. Once on the market, a product may become associated with previously undetected adverse effects and/or may develop manufacturing difficulties. As a result of any of these or other problems, a product's regulatory approval could be withdrawn, which could harm our business and operating results. In addition, we must establish and maintain an effective healthcare compliance program in order to comply with U.S. and other laws applicable to marketed drug products. U.S. laws such as the Foreign Corrupt Practices Act prohibit the offering or payment of bribes or inducements to foreign public officials, including potentially physicians or other medical professionals who are employees of public health care entities. In addition, many countries have their own laws similar to the healthcare compliance laws that exist in the U.S. Implementing an effective compliance program requires the expenditure of significant time and resources. If we are found to be in violation of any of these laws, we may be subject to significant penalties, including but not limited to civil or criminal penalties, damages and fines as well as exclusion from government healthcare programs.

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

We intend to have OMIDRIA and our product candidates, if approved, marketed outside the U.S. In order to market our products in non-U.S. jurisdictions, we or our partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The regulatory approval procedure varies among countries and can involve additional testing and data review. The requirements governing marketing authorization, the conduct of clinical trials, pricing and reimbursement vary from country to country. Approval by the FDA or the European Medicines Agency, or EMA, does not ensure approval by regulatory agencies in other jurisdictions, and approval by one foreign regulatory authority does not ensure approval by

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regulatory agencies in other foreign countries or by the FDA. The time required to obtain regulatory approval outside the U.S. and EU may differ from that required to obtain FDA or EMA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these "Risk Factors" and we may not obtain foreign regulatory approvals on a timely basis, or at all.

If OMIDRIA and/or our product candidates, if approved, are marketed outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We may be subject to additional risks if OMIDRIA and/or our product candidates, if approved, are marketed outside the U.S., including:

- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

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

Manufacturing under our existing OMIDRIA manufacturing agreement with Patheon ceased at the end of 2015. Validation of the manufacturing process for OMIDRIA under our Hospira supply agreement has not been completed. We do not presently have an alternate manufacturing facility for OMIDRIA in operation and we do not expect that any OMIDRIA manufacturing facility will be approved for production before 2017 at the earliest. We anticipated this transition and increased production of OMIDRIA prior to the break in manufacturing, and believe that we will have sufficient supply to meet product needs until OMIDRIA production is recommenced. However, we can provide no assurances if or when the Hospira

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manufacturing facility or any alternate manufacturing facility for OMIDRIA will be in production or whether we can meet market demand for OMIDRIA if demand is greater than we anticipate. Additionally, damage to or destruction of OMIDRIA inventory, including inventory warehoused at our third-party logistics provider, could also adversely affect our ability to meet market demand. We have obtained insurance coverage for the replacement cost of damaged or destroyed OMIDRIA inventory but such coverage would not compensate us for any resulting loss of sales revenue or a reduction in gross margin.

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

We and our third-party manufacturers must obtain from third-party suppliers the active pharmaceutical ingredients, excipients and primary and secondary packaging materials necessary for our contract manufacturers to produce OMIDRIA and our PharmacoSurgery product candidates for our clinical trials and, to the extent approved or commercialized, for commercial distribution. Although we have entered or intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of active pharmaceutical ingredients, excipients and materials for OMIDRIA and our PharmacoSurgery product candidates, we have not yet entered into agreements for the supply of all such ingredients, excipients or materials, and we may be unable to secure all such supply agreements or guarantees on commercially reasonable terms, if at all. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients, excipients or materials in a timely manner or in the quantities required. If we or our third-party manufacturers are unable to obtain the quantities of these ingredients, excipients or materials that are necessary for the manufacture of commercial supplies of OMIDRIA, our ability to generate revenue from the sale of OMIDRIA would be materially and adversely affected. Further, if we or our third-party manufacturers are unable to obtain active pharmaceutical ingredients, excipients and materials as necessary for our clinical trials or for the manufacture of commercial supplies of our product candidates, if approved, potential regulatory approval or commercialization would be delayed, which would materially and adversely affect our ability to generate revenue from the sale of our product candidates.

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

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

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

- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials;
- the suspension by a regulatory agency of a trial put on a clinical hold; and
- the amendment of clinical trial protocols to reflect changes in regulatory requirements and guidance or other reasons as well as subsequent re-examination of amendments of clinical trial protocols by Institutional Review Boards or Ethics Committees.

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

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

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

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

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

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our products and product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the U.S., or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the U.S. or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and product candidates and/or materially harm our business.

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

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs, including our GPCR program;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will be sufficient to protect our technology, provide us with a basis for commercially viable products or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws; or
- if issued, the patents under which we hold rights may not be valid or enforceable.

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

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

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

If we choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, our lawsuit against such an entity could result in a finding that some or all of the claims of one or more of our relevant patents are invalid, unenforceable and/or not infringed, and could also result in a generic version of OMIDRIA being launched after the expiration of the mandatory three-year clinical data exclusivity for OMIDRIA. 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 our patents. An adverse outcome in such legal action could have a material negative effect on our financial condition, results of operations and/or stock price. See “Legal Proceedings” under Item 1 of Part II of this Quarterly Report on Form 10-Q for further discussion of our lawsuit against Par.

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

validity enjoyed by issued patents.

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

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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.

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

In June 2015 we entered into the OMS103 Agreement pursuant to which we granted Fagron an exclusive, royalty-free license to the OMS103 intellectual property, manufacturing information and clinical data to manufacture and commercialize OMS103 in the U.S. in exchange for potential future payments based on product revenue and achievement of commercial milestones. As a result of entering into the OMS103 Agreement, we discontinued our OMS103 clinical development program and are dependent on Fagron to commercialize OMS103 in the U.S. We cannot control whether Fagron will fulfill its obligations under the OMS103 Agreement or whether the commercialization of OMS103 will be successful. Fagron has not performed its diligence milestones in the OMS103 Agreement, including initiating sales of OMS103, and we are evaluating our options with respect to the OMS103 Agreement and the OMS103 program. If we elect to pursue arbitration with Fagron, and/or the OMS103 Agreement is terminated, we can provide no assurances that we will be able to enter into another licensing agreement or have sufficient resources to restart clinical development and conduct any clinical trials if desired. Any of the above risks, if realized, could adversely affect our results of operations.

Under Section 503B of the Federal Food, Drug, and Cosmetic Act, registered outsourcing facilities are required to manufacture under GMP and are subject to FDA inspections and audits. They also are not allowed to manufacture a product that is essentially a copy of one or more FDA-approved drugs. If a licensed registered outsourcing facility such as Fagron is prohibited from commercializing or from continuing commercial sales of OMS103 following initial commercialization because of violations of any FDA regulations or any other reason, our ability to generate revenue from royalty payments from the licensed registered outsourcing facility and achieve profitability will be adversely affected and the market price of our common stock could decline.

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

We may not achieve commercial success if our competitors, many of whom have significantly more resources and experience than we, market products that are safer, more effective, less expensive or faster to reach the market than OMIDRIA or any future products that we may develop and commercialize. Our competitors also may market a product that proves to be unsafe or ineffective, which may affect the market for our competing product, or future product, regardless of the safety or efficacy of our product. The failure of OMIDRIA or any other future product that we may market to effectively compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, our financial condition and our results of operations.

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

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies other than on the life of Gregory A. Demopulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, without having a readily available and appropriate replacement could delay the execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

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

Our performance is largely dependent on the talents and efforts of highly skilled individuals. Our future success depends on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization. If we are unable to hire and train a sufficient number of qualified employees for any reason, we may not be able to implement our current initiatives or grow effectively. We have in the past maintained a rigorous,

highly selective and time-consuming hiring process. We believe that our approach to hiring has significantly contributed to our success to date. If we do not succeed in attracting qualified personnel and retaining and motivating existing personnel, our existing operations may suffer and we may be unable to grow effectively.

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

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

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

We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product's safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with commercialization of our products and product candidates. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain or maintain such insurance on acceptable terms or that we will be able to secure and maintain increased coverage if the commercialization of OMIDRIA or our product candidates progresses, or that future claims against us will be covered by our product liability insurance. Further, our product liability insurance coverage may not reimburse us or may be insufficient to reimburse us for any or all expenses or losses we may suffer. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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alternate product candidates from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to maintain continued access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, we may not be able to commercialize product candidates from these programs.

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

We have borrowed $70.0 million under the Loan Agreement and pledged substantially all of our assets other than intellectual property (with the exception of the proceeds derived from any intellectual property) as collateral. The Loan Agreement restricts our ability to, among other things, incur indebtedness, grant liens, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, repurchase stock, license our intellectual property for a limited set of our programs without lender approval, pledge our intellectual property and engage in significant business transactions such as a change of control. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities.

The Loan Agreement also requires us to achieve certain minimum net revenue amounts from OMIDRIA through the end of 2018, including achieving net revenues of at least $70.0 million for the 2016 calendar year and at least $25.0 million for each quarter in the 2017 calendar year or, alternatively, maintain at least 50% of the then-outstanding note payable balance in restricted cash and eligible term investments. We recorded net sales of OMIDRIA of $17.3 million for the six months ended June 30, 2016, and we cannot provide assurance that we will generate sufficient revenue from OMIDRIA in the future to satisfy fully the net revenue covenants. We are also required to maintain at least $10.0 million in cash and cash equivalents during the term of the Loan Agreement. The failure to satisfy these or other obligations under the Loan Agreement would constitute an event of default. An event of default under the Loan Agreement also 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 an inability to repay the loan. If there is an event of default under the Loan Agreement, the lenders may have the right to accelerate all of our repayment obligations under the Loan Agreement and to take control of our pledged assets, which include our cash, cash equivalents and short-term investments. Upon the acceleration of the loan, we will be required to repay the loan immediately or to attempt to reverse the declaration through negotiation or litigation. 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. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline. If we raise any additional debt financing, the terms of such debt could further restrict our operating and financial flexibility.

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

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

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

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

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

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attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Risks Related to Our Common Stock

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

During the 12-month period ended June 30, 2016, our stock traded as high as $30.23 per share and as low as $8.90 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to numerous factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

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

To the extent that we raise additional funds in the future by issuing equity securities, including pursuant to our ATM Agreement with JonesTrading, our shareholders would experience dilution, which may be significant and could cause the market price of our common stock to decline significantly. In addition, approximately 9.6 million shares of common stock as of June 30, 2016 subject to outstanding options and warrants may become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements. Further, as of June 30, 2016 we also had approximately 1.9 million shares of common stock reserved for future issuance under our employee benefit plans that are not subject to outstanding options. If the holders of these outstanding options or warrants elect to exercise some or all of them, or if the shares subject to our employee benefit plans are issued and become eligible for sale in the public market, our shareholders would experience dilution and the market price of our common stock could decline.

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

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

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

Our business requires significant funding. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Additionally, under the Loan Agreement, we have agreed not to pay any dividends. Therefore, we currently do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a rise in the market price of our common stock, which is uncertain and unpredictable, will be the sole source of potential gain for shareholders in the foreseeable future, and an investment in our common

stock for dividend income should not be relied upon.

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

(a) Unregistered Sales of Equity Securities. On May 18, 2016, we issued warrants to Oxford and EWB, or the Warrants, to purchase an aggregate of 100,602 shares of our common stock in connection with the Amendment. The Warrants are exercisable for seven years at an exercise price per share of $9.94. The Warrants were issued under the exemption from registration provided by Section 4(a)(2) of the Securities Act. No underwriters were involved in the issuance of the Warrants and no commissions were paid in connection with such issuances.

ITEM 6. EXHIBITS

Exhibit Number	Description
4.1(1)	Form of Omeros Corporation Warrant to Purchase Common Stock
10.1(2)	First Amendment to Loan and Security Agreement between Omeros and Oxford Finance LLC, as collateral agent and as a lender, and East West Bank, as a lender, dated May 16, 2016
10.2(3)	Form of Secured Promissory Note issued by Omeros to Oxford Finance LLC and to East West Bank
12.1	Ratio of Earnings to Fixed Charges
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to Exhibit 10.3 of the registrant's Current Report on Form 8-K filed on May 19, 2016 (File No. 001-34475).

(2) Incorporated by reference to Exhibit 10.1 of the registrant's Current Report on Form 8-K filed on May 19, 2016 (File No. 001-34475).

(3) Incorporated by reference to Exhibit 10.2 of the registrant's Current Report on Form 8-K filed on May 19, 2016 (File No. 001-34475).

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SIGNATURES

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

OMEROS CORPORATION

Dated: August 9, 2016 /s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D.
President, Chief Executive Officer and Chairman of the Board of Directors

Dated: August 9, 2016 /s/ Michael A. Jacobsen
Michael A. Jacobsen
Vice President, Finance, Chief Accounting Officer and Treasurer