

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017
or

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

For the transition period from _____ to _____
Commission file number: 001-34475

OMEROS CORPORATION

(Exact name of registrant as specified in its charter)

Washington
(State or other jurisdiction of
incorporation or organization)

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

**201 Elliott Avenue West
Seattle, Washington**
(Address of principal executive offices)

98119
(Zip Code)

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of November 6, 2017, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 48,003,770.

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,” “likely,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would,” and similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

- our plans for sales, marketing and distribution of OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3%;
 - our ability to obtain separate or similar reimbursement for OMIDRIA from the Centers for Medicare and Medicaid Services, or CMS, beyond January 1, 2018 and/or to extend the pass-through period, our expectations that OMIDRIA would be part of the packaged payment for Medicare patients in the event that we do not obtain separate or similar reimbursement for OMIDRIA, and our expectations regarding the eventual per unit price and net product revenues we may receive for OMIDRIA in the future;
 - our expectations regarding our product sales and our estimates 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 Term Loan Agreement, or the CRG Loan Agreement, with CRG Servicing LLC, or CRG, and the lenders identified therein;
 - 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 ability to design, initiate and/or 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, for OMS824 and for OMS527;
 - in our OMS721 program, our expectations regarding: whether enrollment in any or all planned Phase 3 clinical trials will proceed as expected; whether accelerated approval, fast track designation, breakthrough therapy designation and/or orphan drug designation may be granted by the U.S. Food and Drug Administration, or FDA, or Priority Medicines designation or orphan designation may be granted by the European Medicines Agency, or EMA, for indications for which we are pursuing such approval or designation; and Phase 3 clinical trial design in patients with immunoglobulin A nephropathy and related potential label claims;
 - 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, and our ability to effect any such arrangement with respect to OMIDRIA in the European Union, or EU, and place OMIDRIA on the market in at least one European Economic Area, or EEA, country prior to July 28, 2018;
 - our ability to raise additional capital through the capital markets, including under our at-the-market equity facility with JonesTrading Institutional Services LLC, or JonesTrading, or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;
 - our expectations about the commercial competition that OMIDRIA and our product candidates, if commercialized, face or may face;
 - 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 merits, 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, including but not limited to our patent infringement lawsuits against Sandoz, Inc., or Sandoz, and against Lupin Ltd. and Lupin Pharmaceuticals, Inc., which we refer to collectively as Lupin;
 - our expectation that the OMIDRIAssure® Reimbursement Services Program will continue to 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 to what extent the dosing limitations in our OMS824 program may be removed, if at all;
-

Table of Contents

- *the factors on which we base our estimates for accounting purposes and our expectations regarding the effect of changes in accounting guidance or standards on our operating results;*
- *the implementation of an enterprise resource planning system; 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 1A of Part II of this Quarterly Report on Form 10-Q under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in our other filings with the Securities and Exchange Commission, or SEC. Given these risks, uncertainties and other factors, actual results or anticipated developments may not be realized or, even if substantially realized, may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements, which represent our estimates and assumptions only as of the date of the filing of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable law, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

[Table of Contents](#)

OMEROS CORPORATION
FORM 10-Q FOR THE QUARTER ENDED September 30, 2017

INDEX

	<u>Page</u>
<u>Part I — Financial Information</u>	<u>3</u>
Item 1. Financial Statements (unaudited)	3
Condensed Consolidated Balance Sheets	3
Condensed Consolidated Statements of Operations and Comprehensive Loss	4
Condensed Consolidated Statements of Cash Flows	5
Notes to Condensed Consolidated Financial Statements	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3. Quantitative and Qualitative Disclosures About Market Risk	24
Item 4. Controls and Procedures	24
<u>Part II — Other Information</u>	<u>25</u>
Item 1. Legal Proceedings	25
Item 1A. Risk Factors	25
Item 6. Exhibits	39
<u>Signatures</u>	<u>40</u>

[Table of Contents](#)

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

OMEROS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

(unaudited)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,026	\$ 2,224
Short-term investments	85,787	43,107
Receivables	24,571	12,037
Inventory	822	1,128
Prepaid expense	5,691	1,766
Total current assets	117,897	60,262
Property and equipment, net	1,785	1,181
Restricted cash and investments	5,835	5,835
Total assets	\$ 125,517	\$ 67,278
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 3,680	\$ 2,519
Accrued expenses	20,261	13,252
Current portion of deferred rent	381	102
Current portion of lease financing obligations	368	198
Total current liabilities	24,690	16,071
Notes payable and lease financing obligations, net	82,778	79,512
Deferred rent	8,838	9,142
Commitments and contingencies (Note 8)		
Shareholders' equity (deficit):		
Preferred stock, par value \$0.01 per share, 20,000,000 shares authorized and none issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock, par value \$0.01 per share, 150,000,000 authorized; 47,986,443 and 43,819,133 issued and outstanding at September 30, 2017 and December 31, 2016, respectively	480	438
Additional paid-in capital	515,548	432,002
Accumulated deficit	(506,817)	(469,887)
Total shareholders' equity (deficit)	9,211	(37,447)
Total liabilities and shareholders' equity	\$ 125,517	\$ 67,278

See notes to condensed consolidated financial statements

OMEROS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues				
Product sales, net	\$ 21,658	\$ 11,289	\$ 51,067	\$ 28,539
Grant revenue	—	—	—	173
Total revenue	21,658	11,289	51,067	28,712
Costs and expenses				
Cost of product sales	184	378	613	1,032
Research and development	14,835	12,492	40,212	38,157
Selling, general and administrative	11,749	10,457	40,016	31,942
Total costs and expenses	26,768	23,327	80,841	71,131
Loss from operations	(5,110)	(12,038)	(29,774)	(42,419)
Interest expense	(2,780)	(2,135)	(8,166)	(5,367)
Other income, net	408	211	1,010	673
Net loss	\$ (7,482)	\$ (13,962)	\$ (36,930)	\$ (47,113)
Comprehensive loss	\$ (7,482)	\$ (13,962)	\$ (36,930)	\$ (47,113)
Basic and diluted net loss per share	\$ (0.16)	\$ (0.34)	\$ (0.83)	\$ (1.19)
Weighted-average shares used to compute basic and diluted net loss per share	46,262,211	41,058,754	44,709,418	39,518,128

See notes to condensed consolidated financial statements

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

	Nine Months Ended September 30,	
	2017	2016
Operating activities:		
Net loss	\$ (36,930)	\$ (47,113)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	378	211
Stock-based compensation expense	9,449	9,566
Non-cash interest expense	3,056	1,195
Changes in operating assets and liabilities:		
Receivables	(12,534)	(3,940)
Inventory	306	(924)
Prepaid expenses and other assets	(3,925)	685
Accounts payable, accrued expenses, and deferred rent	8,145	(321)
Net cash used in operating activities	(32,055)	(40,641)
Investing activities:		
Purchases of property and equipment	(350)	(78)
Purchases of investments	(65,109)	(58,121)
Proceeds from the sale and maturities of investments	22,429	47,875
Net cash used in investing activities	(43,030)	(10,324)
Financing activities:		
Proceeds from issuance of common stock	63,627	38,003
Proceeds from borrowings under notes payable	—	19,864
Payments on notes payable and lease financing obligations	(252)	(62)
Increase in restricted cash and investments	—	(156)
Proceeds upon exercise of stock options	10,512	2,248
Net cash provided by financing activities	73,887	59,897
Net decrease (increase) in cash and cash equivalents	(1,198)	8,932
Cash and cash equivalents at beginning of period	2,224	1,365
Cash and cash equivalents at end of period	\$ 1,026	\$ 10,297
Supplemental cash flow information		
Cash paid for interest	\$ 5,110	\$ 3,629
Conversion of accrued interest to notes payable	\$ 2,467	\$ —
Property acquired under capital lease	\$ 632	\$ 388
Issuance of warrants in connection with amendment to notes payable	\$ —	\$ 758

See notes to condensed consolidated financial statements

OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases 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) and in the European Economic Area for use during cataract surgery or intraocular lens replacement.

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 September 30, 2017 and for the three and nine months ended September 30, 2017 and 2016 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2016 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, 2016, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 16, 2017.

Liquidity

We have had a history of net losses and use of cash for operations (\$36.9 million and \$32.1 million, respectively, for the nine months ended September 30, 2017). As of September 30, 2017 we had \$86.8 million in cash, cash equivalents and short-term investments. In addition, we expect to collect the \$24.6 million of accounts receivable outstanding as of September 30, 2017 and have the ability, at our election and subject to only customary closing conditions, to borrow an additional \$45.0 million under our Term Loan Agreement, or the CRG Loan Agreement, with CRG Servicing LLC, or CRG, and the lenders identified therein, on or prior to March 21, 2018. We believe our assets and these incremental sources of funds are adequate to fund our future financial obligations as they become due through November 9, 2018 regardless of the outcome of the separate-payment status for Medicare patients treated with our commercial product, OMIDRIA. This pass-through status for Medicare patients is due to expire on January 1, 2018. Therefore we have determined that the conditions that raised substantial doubt about our ability to meet our financial obligations as they become due that existed in prior interim periods do not currently exist. This derived result may change in the future based on changes in conditions and/or events impacting our liquidity.

Product Sales, Net

We record revenue from product sales when the product is delivered to our wholesalers. Product sales to a wholesaler are not recorded if we determine that the wholesaler's on-hand OMIDRIA inventory, based on sell-through and inventory information we regularly receive from our wholesalers, exceeds approximately eight weeks of projected demand.

Product sales are recorded net of wholesaler distribution fees and estimated chargebacks, product returns, rebates and purchase volume discounts. Accruals or allowances are established for these deductions in the same period when revenue is recognized, and actual amounts incurred are offset against the applicable accruals or allowances. We reflect each of these accruals or allowances as either a reduction in the related account receivable or as an accrued liability, depending on how the amount is expected to be 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

[Table of Contents](#)

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.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, (FASB), issued amended guidance related to revenue from contracts with customers. The amended guidance introduces a new principles-based framework for revenue recognition and disclosure. Since its issuance FASB has issued five Accounting Standards Updates, (ASUs), amending the guidance and effective date, and the SEC has rescinded certain related guidance. The current effective date of the guidance requires us to adopt the standard by January 1, 2018 using either a modified retrospective method or a full retrospective method of transition. We currently anticipate adopting the guidance January 1, 2018 under the modified retrospective method and do not anticipate a material impact on our revenue recognition practices as all of our revenue arrangements consists of a single performance obligation to transfer promised goods and we currently recognize revenue when the goods are transferred.

In February 2016, the 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 method and is effective for all annual and interim periods beginning after December 15, 2018. Earlier adoption is permitted. While we are still in the process of evaluating the effect of adoption on our consolidated financial statements and are currently assessing our leases, we expect to adopt the standard January 1, 2019. The adoption will lead to an increase in the assets and liabilities recorded on our Condensed Consolidated Balance Sheets primarily due to the lease agreements for our office building and vehicle leases.

In May 2016, the FASB issued ASU 2017-09, Compensation - Stock Compensation (Topic 718), which effectively amends previous issued guidance and provides clarity and consistency in practice on the accounting for changes to the terms and conditions of stock-based payment arrangement. This standard is effective for all annual and interim periods beginning after December 15, 2017 and is applied prospectively to modifications occurring after the adoption date. Earlier adoption is permitted. We do not anticipate a material change upon adoption.

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. Common share equivalents are excluded from the diluted net loss per share computation if their effect is anti-dilutive.

The basic and diluted net loss per share amounts for the three and nine months ended September 30, 2017 and 2016 were computed based on the shares of common stock outstanding during the respective periods. Potentially dilutive securities excluded from the diluted loss per share calculation are as follows:

	September 30,	
	2017	2016
Outstanding options to purchase common stock	9,813,462	9,336,681
Outstanding warrants to purchase common stock	100,602	100,602
Total	9,914,064	9,437,283

Note 3—Cash, Cash Equivalents and Investments

As of September 30, 2017 and December 31, 2016, all investments are classified as short-term and available-for-sale on the accompanying Condensed Consolidated Balance Sheets. 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;

[Table of Contents](#)

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

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

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

	September 30, 2017			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	\$ 5,835	\$ —	\$ —	\$ 5,835
Money-market funds classified as short-term investments	85,787	—	—	85,787
Total	<u>\$ 91,622</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 91,622</u>

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	\$ 5,835	\$ —	\$ —	\$ 5,835
Money-market funds classified as short-term investments	43,107	—	—	43,107
Total	<u>\$ 48,942</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 48,942</u>

Cash held in demand deposit accounts of \$1.0 million and \$2.2 million is excluded from our fair-value hierarchy disclosure as of September 30, 2017 and December 31, 2016, respectively. There were no unrealized gains or losses associated with our short-term investments as of September 30, 2017 or December 31, 2016. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets for receivables, accounts payable, other current monetary assets and liabilities and notes payable and lease financing obligations approximate fair value.

Note 5—Inventory

The components of inventory are as follows:

	September 30, 2017	December 31, 2016
	(In thousands)	
Raw materials	\$ 101	\$ 101
Work-in-process	378	854
Finished goods	343	173
Total inventory	<u>\$ 822</u>	<u>\$ 1,128</u>

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

[Table of Contents](#)

Note 6—Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2017	December 31, 2016
(In thousands)		
Contract research and development	\$ 7,726	\$ 3,030
Sales rebates and discounts	5,242	1,335
Consulting and professional fees	2,289	2,223
Employee compensation	1,970	4,551
Clinical trials	1,350	1,167
Other accruals	1,684	946
Total accrued liabilities	<u>\$ 20,261</u>	<u>\$ 13,252</u>

Note 7—Notes Payable

Notes payable and lease financing obligations consist of the following:

	September 30, 2017	December 31, 2016
(In thousands)		
Notes payable	\$ 82,983	\$ 80,516
Lender facility fee payable upon maturity	4,149	4,025
Lease financing obligations	901	522
Notes payable, facility fee and lease financing obligations	88,033	85,063
Unamortized debt discount	(3,644)	(3,958)
Unamortized debt issuance costs	(1,243)	(1,395)
Current portion of lease financing obligations	(368)	(198)
Non-current portion of notes payable and lease financing obligations, net	<u>\$ 82,778</u>	<u>\$ 79,512</u>

In October 2016, we entered into the CRG Loan Agreement, which requires that we make interest-only payments through December 31, 2020. Subject to the achievement of certain milestones, this interest-only period potentially could be extended through the maturity date of September 30, 2022. In November 2016, we borrowed \$80.0 million under the CRG Loan Agreement and repaid our then-outstanding notes payable.

In October 2017, we and CRG amended the CRG Loan Agreement so that we will be permitted to borrow, at our sole discretion and subject to customary closing conditions, up to an additional \$45.0 million available through March 21, 2018.

The CRG Loan Agreement accrues interest at an annual rate of 12.25% (4.00% of which can be deferred at our option through December 31, 2020 by adding such amount to the aggregate principal amount). As of September 30, 2017, as allowed under the CRG Loan Agreement, we have deferred \$3.0 million (\$2.5 million for the nine months ended September 30, 2017) of interest due by increasing the principal amount outstanding. The CRG Loan Agreement requires us to maintain cash and cash equivalents of \$5.0 million during the term of the agreement which is recorded as restricted cash and investments in our Condensed Consolidated Balance Sheet.

We are also required to pay a facility fee equal to 5.00% of the aggregate principal amount borrowed (including principal additions related to deferred interest) on repayment of the CRG Loan Agreement. The facility fee is being accreted to notes payable using the effective interest method over the term of the CRG Loan Agreement.

We may prepay all or a portion of the outstanding principal under the CRG Loan Agreement at any time upon prior notice subject to a prepayment fee through September 30, 2019, with no prepayment fee being owed thereafter. In certain circumstances, including a change of control and certain asset sales or licensing transactions, we are required to prepay all or a portion of the loan, including the applicable prepayment premium on the outstanding principal to be prepaid.

[Table of Contents](#)

The CRG Loan Agreement requires us to achieve either (a) minimum net revenue amounts through the end of 2021, which are \$55.0 million and \$65.0 million for the 2017 and 2018 calendar years, respectively, or (b) a minimum market capitalization threshold equal to the product of 6.4 multiplied by the aggregate principal amount of loans outstanding under the CRG Loan Agreement, determined as of the fifth business day following announcement of earnings results for the applicable year. If we are unable to satisfy the minimum annual revenue requirement or the market capitalization threshold for any given year, we may avoid a related default by repaying the shortfall between actual revenues and the minimum revenue requirement for such year using proceeds generated by an equity or subordinated debt issuance. We anticipate achieving the minimum net revenue requirement of \$55.0 million for the 2017 calendar year.

The CRG Loan Agreement includes customary events of default (see Note 7 of the “Notes to Consolidated Financial Statements” included in our Annual Report on Form 10-K for the year ended December 31, 2016). If there is an event of default the lenders may have the right to accelerate all of our repayment obligations under the CRG Loan Agreement and to take control of our pledged assets, which consists of substantially all of our assets including our intellectual property. Under certain circumstances, a default interest rate of an additional 4.00% per annum will apply to all outstanding obligations during the existence of an event of default. There was no event of default under the CRG Loan Agreement as of September 30, 2017.

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 8 to our Consolidated Financial Statements for the year ended December 31, 2016 included in our Annual Report on Form 10-K.

Contracts

We have various agreements with third parties that collectively require payment of termination fees totaling \$3.8 million as of September 30, 2017 if we cancel work within specific time frames, either prior to commencing or during performance of the contracted services. This is in addition to fees associated with the CRG Loan Agreement (see Note 7) and within the Contractual Obligations and Commitments and Financial Condition - Liquidity and Capital Resources sections of Management’s Discussion and Analysis.

Litigation

As described within Note 8 of the “Notes to Consolidated Financial Statements” included in our Annual Report on Form 10-K for the year ended December 31, 2016, we filed a patent infringement lawsuit against Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC (collectively, Par) in September 2015. A bench trial in the U.S. District Court for the District of Delaware was held on this matter on July 5-7, 2017 and on October 4, 2017 we entered into a settlement agreement and consent judgment with Par, pursuant to which Par acknowledged and confirmed the validity of our U.S. patents related to OMIDRIA. In accordance with the consent judgment, Par and its affiliates are prohibited from launching a generic version of OMIDRIA until the earlier of April 1, 2032 or a date on which we or a third party, through licensing or any future final legal judgment with respect to our U.S. OMIDRIA patents, is able to launch a generic version of OMIDRIA. Under the settlement agreement, Par is granted a non-exclusive, non-sublicensable license to make, sell and distribute a generic version of OMIDRIA between the permitted launch date and the latest expiration of our U.S. patents related to OMIDRIA (*i.e.*, October 23, 2033). During this period, Par is required to pay us a royalty equal to 15% of Par’s net sales of its generic version of OMIDRIA. For more information regarding the settlement agreement and consent judgment, see Part II, Item 1, “Legal Proceedings.”

In May 2017, we received Notice Letters from Sandoz Inc. (Sandoz) and Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, Lupin), respectively, that Sandoz and Lupin had each filed an ANDA containing a Paragraph IV Certification under the Hatch-Waxman Act seeking approval from the FDA to market a generic version of OMIDRIA prior to the expiration our patents covering OMIDRIA. On June 21, 2017, we filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware and a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Sandoz and on June 22, 2017 we filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware and a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Lupin. The Delaware lawsuits against Sandoz and Lupin were consolidated for all purposes by court order entered October 16, 2017, and the New Jersey lawsuits were dismissed by agreement of the parties on October 13, 2017. Sandoz has filed an answer to our Delaware lawsuit asserting defenses of patent invalidity. Lupin has filed an answer to our Delaware lawsuit asserting defenses and counterclaims for declaratory judgment of patent invalidity and non-infringement. The assertions raised in Sandoz’s and Lupin’s Paragraph IV

[Table of Contents](#)

Notice Letters and their answers to our lawsuits are substantially similar to those raised by Par in the above-described patent litigation matter against Par. For more information regarding these lawsuits, see Part II, Item 1, “Legal Proceedings.” We believe the assertions in the Sandoz and Lupin Paragraph IV Notice Letters and the answers to our lawsuits do not have merit, and we intend to prosecute vigorously our infringement claims against each of Sandoz and Lupin.

Note 9—Shareholders’ Equity

Securities Offering

In August 2017, we sold 3.0 million shares of our common stock at a public offering price of \$22.75 per share. After deducting underwriter discounts and offering expenses of \$4.6 million, we received net proceeds from the transaction of \$63.6 million.

Common Stock

For the nine months ended September 30, 2017, we received proceeds of \$10.5 million upon the exercise of stock options which resulted in the issuance of 1,167,310 shares of common stock. For the nine months ended September 30, 2016, we received proceeds of \$2.2 million upon the exercise of stock options and warrants which resulted in the issuance of 1,326,773 shares of common stock.

We did not sell any shares of our common stock under the At Market Issuance Sales Agreement (the ATM Agreement) with JonesTrading Institutional Services LLC during the three or nine months ended September 30, 2017 and sold 64,565 shares at an average price of \$11.41 per share and received net proceeds of \$724,000 during the nine months ended September 30, 2016. We are currently permitted to sell shares of our common stock having an aggregate offering amount of up to \$50.0 million under the ATM Agreement.

Warrants

In connection with an amendment of the then-outstanding loan agreement with Oxford Finance LLC and East West Bank on May 18, 2016, we issued warrants to purchase an aggregate of 100,602 shares of our common stock. As of September 30, 2017, these warrants remained outstanding and are exercisable through May 18, 2023 at an exercise price of \$9.94 per share.

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Research and development	\$ 1,297	\$ 1,156	\$ 4,034	\$ 4,530
Selling, general and administrative	1,744	1,379	5,415	5,036
Total	\$ 3,041	\$ 2,535	\$ 9,449	\$ 9,566

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Estimated weighted-average fair value	\$ 13.66	\$ 7.42	\$ 8.38	\$ 6.94
Weighted-average assumptions				
Expected volatility	74%	73%	74%	74%
Expected term, in years	6.1	6.0	6.0	5.7
Risk-free interest rate	1.95%	1.25%	1.99%	1.35%
Expected dividend yield	—%	—%	—%	—%

[Table of Contents](#)

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, 2016	9,809,374	\$ 9.66		
Granted	1,734,890	12.70		
Exercised	(1,167,310)	9.01		
Forfeited	(563,492)	10.97		
Balance at September 30, 2017	9,813,462	\$ 10.19	6.91	\$ 112,232
Vested and expected to vest at September 30, 2017	9,487,171	\$ 10.12	6.84	\$ 109,169
Exercisable at September 30, 2017	6,669,382	\$ 9.33	5.95	\$ 81,994

At September 30, 2017, excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with our unvested options is \$20.5 million, and 3,529,300 shares were available to grant.

2017 Omnibus Incentive Compensation Plan - On June 16, 2017, our shareholders approved the Omeros Corporation 2017 Omnibus Incentive Compensation Plan (the 2017 Plan), which provides for the grant of incentive and non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, performance shares and other stock and cash awards to employees, directors and consultants and subsidiary corporations' employees and consultants. The 2017 Plan replaces the Omeros Corporation 2008 Equity Incentive Plan (the 2008 Plan) and as a result we will not grant any new awards under the 2008 Plan. Any stock option awards granted under the 2008 Plan that were outstanding as of the effective date of the 2017 Plan remain in effect pursuant to their terms and, if the award terminates or is repurchased, the shares underlying such award become available for grant under the 2017 Plan. Under the 2017 Plan, stock options must be granted with exercise prices not less than the fair market value of the common stock subject to the stock option on the date of the grant (and, in some cases, not less than 110% of such fair market value). The term of stock options granted under the 2017 Plan may not exceed 10 years and, in some cases, may not exceed five years.

[Table of Contents](#)

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

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

Overview

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

Our drug product OMIDRIA® is marketed in the U.S. 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 PharmacoSurgery platform is based on low-dose combinations of FDA-approved therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery.

In our pipeline we have clinical-stage development programs focused on: complement-associated thrombotic microangiopathies; complement-mediated glomerulonephropathies; Huntington's disease and cognitive impairment; and addictive and compulsive disorders. 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. We launched OMIDRIA in the U.S. in the second quarter of 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 November 2017, CMS issued its 2018 Hospital Outpatient Prospective Payment System Final Rule, effective January 1, 2018, under which OMIDRIA would no longer have separate payment under Medicare Part B and consequently would be included as part of the packaged procedural payment. We are working through legislative and administrative means to obtain a continuation of separate or similar reimbursement for OMIDRIA on and after January 1, 2018 and/or to extend the pass-through period; however, in the event that none of these approaches is successful, we expect that OMIDRIA will be included as part of the packaged procedural payment and, as a result, the per unit price, as well as our net revenues, we receive for OMIDRIA would likely be reduced eventually, potentially by a significant amount. For more information regarding OMIDRIA reimbursement, see "Results of Operations" below.

We completed an OMIDRIA pediatric clinical trial in 2016 that was conducted to fulfill the FDA's post-marketing requirement as well as a written request from the FDA to conduct a pediatric study. Successful completion of the trial, including submission of a supplemental New Drug Application, or sNDA, that includes the full clinical study report and proposed labeling, plus confirmation by the FDA that the submission fulfills the FDA's written request, results in eligibility for an additional six months of marketing exclusivity for OMIDRIA and label expansion to include information on dosing for pediatric patients. We have submitted an sNDA, with results of the pediatric study included in proposed label language. Although conducted in patients newborn to three years old, the FDA agreed that results from this trial can be extrapolated to patients through 18 years of age, and a label expansion, if any, would be expected to be applicable to that full age range.

Outside of the U.S., we have received approval from the European Commission, or EC, to market OMIDRIA in the EEA 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. For the European OMIDRIA marketing authorization to remain valid, product must be placed on the market (*i.e.*, released into the distribution chain) in at least one EEA country by July 28, 2018. Decisions about price and reimbursement for OMIDRIA are made on a country-by-country basis and may be required before marketing may occur in a particular country. We do not expect to see sales of OMIDRIA in any countries within the EEA and other international territories if we are unable to either enter into partnerships for the marketing and distribution of OMIDRIA or complete an independent launch in such countries within the EEA. Timing of any such partnerships or

[Table of Contents](#)

independent launch depends on numerous factors, including completion of mutual diligence exercises and domestic sales of OMIDRIA or entry into suitable agreements with contract service vendors, respectively. In addition, we have an exclusive supply and distribution agreement for the sale of OMIDRIA in certain countries in the Middle East, including the Kingdom of Saudi Arabia and the United Arab Emirates, under which sales began on a limited basis in the Kingdom of Saudi Arabia in 2016.

In October 2017, we entered into a Settlement Agreement, or the Settlement Agreement, and consent judgment with Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC, or collectively, Par, resolving our patent litigation against Par that arose from Par's filing of an Abbreviated New Drug Application, or ANDA, seeking approval from the FDA to market a generic version of OMIDRIA. Pursuant to the Settlement Agreement, Par, which had previously stipulated to infringement, acknowledged and confirmed the validity of each of the patents listed in the Orange Book for OMIDRIA. In accordance with the terms of the Settlement Agreement, the U.S. District Court for the District of Delaware signed and entered a consent judgment on October 5, 2017, pursuant to which Par and its affiliates are prohibited from launching a generic version of OMIDRIA until the earlier of April 1, 2032 or a date on which the Company or a third party, through licensing or any future final legal judgment, should one ever exist, with respect to the Orange Book listed patents, is able to launch a generic version of OMIDRIA, as further detailed in the Settlement Agreement, or the Entry Date. Under the Settlement Agreement, we granted Par a non-exclusive, non-sublicensable license to make, sell and distribute a generic version of OMIDRIA between the Entry Date and the latest expiration of our U.S. patents related to OMIDRIA (*i.e.*, October 23, 2033). During this period, Par will pay us a royalty equal to 15% of Par's net sales of its generic version of OMIDRIA. For more information regarding this matter, see Part II, Item 1, "Legal Proceedings."

In May 2017, we received a Notice Letter from Sandoz, Inc., or Sandoz, and a Notice Letter from Lupin Ltd. and Lupin Pharmaceuticals, Inc., which we refer to collectively as Lupin, stating that each of Sandoz and Lupin had filed with the FDA an ANDA containing a Paragraph IV Certification under the Hatch-Waxman Act seeking approval to market a generic version of OMIDRIA prior to the expiration of six Orange Book Patents. On June 21, 2017, Omeros filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Sandoz and on June 22, 2017, Omeros filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Lupin. The Delaware lawsuits against Sandoz and Lupin were consolidated for all purposes by court order in October 2017. For more information regarding these matters, see Part II, Item 1, "Legal Proceedings."

Product Candidates. We have the following clinical-stage programs in our pipeline:

- *MASP-2 - OMS721.* OMS721 is our lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2, or MASP-2, the effector enzyme of the lectin pathway of the complement system. OMS721 is being developed for diseases in which the lectin pathway 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, and hematopoietic stem-cell transplant, or HSCT, -related TMA. We have a Phase 3 clinical program in patients with aHUS and enrollment has opened in the Phase 3 clinical trial in this indication. The Phase 3 clinical program in patients with aHUS consists of one clinical trial - a single-arm (*i.e.*, no control arm), open-label trial in patients with newly diagnosed or ongoing aHUS.

We have a Phase 3 program for OMS721 in patients with IgA nephropathy and recently met with the FDA to discuss Phase 3 trial design in follow-up to the FDA's granting breakthrough designation for OMS721 in this indication. The Agency's meeting minutes state that approval can be obtained with a single successful Phase 3 trial with reduction in proteinuria as the primary efficacy endpoint. Depending on the size of the effect on proteinuria, either full approval or accelerated approval is possible. If full approval is granted based on reduction in proteinuria, estimated glomerular filtration rate, or eGFR, will be followed as part of the safety assessment. Any effect of OMS721 on eGFR is likely to result in additional label claims for the product. If, based on the effect on proteinuria, accelerated rather than full approval is granted, marketing of OMS721 would be allowed during which time confirmatory data on long-term effects of OMS721 on eGFR would be collected. These eGFR data, if satisfactory, would then form the basis for full approval. We are targeting the start of enrollment for this year.

In October 2017, we announced the presentation by a trial investigator of a case report of a patient having co-existing HSCT-TMA and graft-versus-host disease, or GvHD, which both resolved following OMS721 treatment. This case was presented at the European Society for Blood and Marrow Transplantation Crash Course on Diagnosis and Treatment of Noninfectious Complications after HCT in Granada, Spain. We plan to initiate a Phase 3 clinical program in HSCT-TMA before year end.

In November 2017, we announced the presentation at the American Society of Nephrology Conference of follow-up data on the four IgA nephropathy patients in the open-label portion of the Phase 2 trial. As previously reported, all four

[Table of Contents](#)

patients demonstrated a substantial reduction in proteinuria during the clinical trial. In the extended (up to one year) follow-up after completion, proteinuria reduction was maintained in three of the four patients. Specifically, those three patients maintained partial remission relative to baseline (76% to 86% decrease in albumin/creatinine ratios, or uACRs) during extended follow-up. After a substantial drop in uACR during the trial, the fourth patient's uACR returned to 88% of baseline at four months post-treatment. eGFR improved in three of the four patients during the extended follow-up, with increases ranging from 7 to 17 mL/min/1.73 m² (up to 57% improvement) relative to baseline. The fourth patient demonstrated stable eGFR relative to baseline. OMS721 was well-tolerated.

In addition, we have continued to enroll patients in our ongoing OMS721 Phase 2 IgA nephropathy clinical trial and in our OMS721 Phase 2 clinical trial in patients with TMAs.

In our OMS721 program, we have received from the FDA orphan drug designation for the prevention (inhibition) of complement-mediated TMAs, fast track designation for the treatment of patients with aHUS, breakthrough therapy designation to OMS721 for the treatment of IgA nephropathy and orphan drug designation in IgA nephropathy. We are seeking breakthrough designation for OMS721 in HSCT-TMA and plan to pursue accelerated approval in one or more of the indications in development. In addition, in Europe we are pursuing orphan designation and Priority Medicines, or PRIME, status for the treatment of IgA nephropathy and PRIME status for the treatment of HSCT-TMA.

- *PDE10 - OMS824 for Huntington's disease and Schizophrenia.* OMS824, our lead phosphodiesterase 10, or PDE10, inhibitor, is in a Phase 2 clinical program for the treatment of Huntington's disease and a Phase 2 clinical program evaluating OMS824 for the treatment of schizophrenia. We are also evaluating other neurological indications for OMS824. Plans for continuation of the OMS824 program will be based on internal ongoing work and on discussions with the FDA. Clinical trials in our Huntington's program may progress, but if so are currently subject to dosing limitations pending agreement with the FDA. Clinical trials evaluating OMS824 in schizophrenia remain suspended at the request of the FDA until we submit to the FDA a protocol for a schizophrenia trial and receive its clearance to proceed.
- *PPAR γ - OMS405.* In our peroxisome proliferator-activated receptor gamma, or PPAR γ , program, Phase 2 clinical trials have been conducted by our collaborators to evaluate a PPAR γ agonist, alone or in combination with other agents, and have yielded positive data in the treatment of addiction to cocaine, heroin and nicotine.

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

- *PDE7 - OMS527.* In our phosphodiesterase 7, or PDE7, program, we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders. We have selected a clinical candidate and have initiated toxicology studies intended to support the submission of an Investigational New Drug application, or IND, or Clinical Trial Application, or CTA, and subsequent clinical trials. We expect to submit an IND or CTA for OMS527 in the first half of 2018.
- *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 preparation for clinical trials, the manufacturing scale-up process is underway and we are evaluating a number of alternative pathway-related disorders (*e.g.*, paroxysmal nocturnal hemoglobinuria, or PNH) as the first clinical indication for OMS906.
- *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 vitro* and *in vivo* preclinical efficacy studies and optimizing compounds for a number of targets including: GPR151, linked to schizophrenia and cognition; GPR161, which is associated with triple negative breast cancer and various sarcomas; GPR183, linked to osteoporosis and to Epstein-Barr virus infections and related diseases; GPR174, which appears to be involved in the modulation of the immune system and, in particular, increases cytokine production and inhibits production of regulatory T cells, or "T-regs," both which are known to be important in autoimmune disease, such as multiple sclerosis, in cancer and in organ transplantation; and OPN4, linked to seasonal affective disorder, mood disorders and photophobia.
- *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. Using our platform and other know-how and techniques, we have generated antibodies to several clinically significant targets, including highly potent antibodies against MASP-3 and MASP-1, and our platform continues to add to our pipeline antibodies against additional important targets.

Table of Contents

PharmacoSurgery Product Candidates. 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 continue to evaluate our options regarding the OMS103 Agreement and our OMS103 program. 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.

Financial Summary

We recognized net losses of \$7.5 million and \$14.0 million for the three months ended September 30, 2017 and 2016, respectively. As of September 30, 2017, our accumulated deficit was \$506.8 million, total shareholders' equity was \$9.2 million and we had \$86.8 million in cash, cash equivalents and short-term investments available for general corporate use. In addition, we had restricted cash and investments of \$5.8 million that we were required to maintain in depository and investment accounts as of September 30, 2017 pursuant to (a) our Term Loan Agreement, or the CRG Loan Agreement, with CRG Servicing LLC, or CRG, and the lenders identified therein, which requires us to maintain a balance of cash and cash equivalents of \$5.0 million, (b) our lease related to the Omeros Building, and (c) our fleet vehicles used by our OMIDRIA sales force.

[Table of Contents](#)

Results of Operations

Revenue

Our revenue consists of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Product sales, net	\$ 21,658	\$ 11,289	\$ 51,067	\$ 28,539
Small Business Innovative Research Grants (SBIR)	—	—	—	173
Total revenue	\$ 21,658	\$ 11,289	\$ 51,067	\$ 28,712

During the three and nine months ended September 30, 2017, OMIDRIA revenue increased \$10.4 million, or 91.9%, and \$22.5 million or 78.9% as compared to the three and nine months ended September 30, 2016. The increase in OMIDRIA sales during the three and nine months ended September 30, 2017 compared to the same periods in 2016 is primarily due to the continued acceptance of OMIDRIA in the ophthalmic surgery community, as evidenced by an increase in the number of ASCs and hospitals purchasing OMIDRIA and increased penetration into existing customer accounts.

As compared to the quarter ended June 30, 2017, OMIDRIA reported revenue increased \$4.5 million, or 26.3%. This increase was due to a higher number of units of OMIDRIA being sold and is primarily attributable to growth in new customers and increased OMIDRIA purchases from our existing customers, due in part to increased participation in the OMIDRIA purchase volume discount program for which ASCs may qualify by meeting or exceeding quarterly purchase volumes of OMIDRIA.

CMS has granted transitional pass-through reimbursement status for OMIDRIA 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. In November 2017, CMS issued its 2018 Hospital Outpatient Prospective Payment System Final Rule, effective January 1, 2018, under which OMIDRIA would no longer have separate payment under Medicare Part B and consequently would be included as part of the packaged procedural payment for Medicare patients. We are seeking to obtain a continuation of separate or similar reimbursement for OMIDRIA on and after January 1, 2018 and/or to extend the pass-through period through legislative and administrative means; however, in the event that neither approach is successful, 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 likely be reduced eventually and our product revenue could be significantly impacted. We are currently unable to predict whether separate or similar reimbursement will be granted or whether an extension of the pass-through period will be granted, or, if granted, the timing of the grant or the actual reimbursement rate. In addition, uncertainty regarding the reimbursement status of OMIDRIA will likely result in new and existing customers delaying purchase decisions and potentially returning unused product during the latter portion of the fourth quarter of 2017 and into 2018 if separate or similar reimbursement or an extension of pass-through is not granted.

Until we have additional clarity on reimbursement for OMIDRIA pass-through reimbursement after January 1, 2018, we cannot determine the impact on OMIDRIA product sales trends through the fourth quarter of 2017 and into 2018.

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. Our total gross-to-net provision for the three and nine months ended September 30, 2017 was 24.7% and 24.2%, respectively of gross OMIDRIA product sales. This compares to 11.6% and 9.3% for the corresponding periods in 2016. The primary reason for the increases in gross-to-net deductions for both periods is an increase in chargebacks and rebates due to our OMIDRIAssure Reimbursement Program and our purchase volume discount program.

A summary of our gross-to-net related accruals for the nine months ended September 30, 2017 is as follows:

[Table of Contents](#)

	Chargebacks and Rebates	Distribution Fees and Product Return Allowances	Total
	(In thousands)		
Balance as of December 31, 2016	\$ 1,629	\$ 481	\$ 2,110
Provisions	13,884	2,407	16,291
Payments	(9,681)	(1,658)	(11,339)
Balance as of September 30, 2017	<u>\$ 5,832</u>	<u>\$ 1,230</u>	<u>\$ 7,062</u>

Chargebacks and Rebates.

We record a provision for estimated chargebacks and rebates at the time we recognize OMIDRIA product sales revenue and reduce the accrual when payments are made or credits are granted. Our chargebacks are related to a Pharmaceutical Pricing Agreement, a Federal Supply Schedule agreement, a 340B prime vendor agreement and a Medicaid Drug Rebate Agreement. We also record a provision for estimated rebates for our OMIDRIA Assure Reimbursement Services Program and our purchase volume discount programs.

Our chargebacks and rebates provision for the three and nine months ended September 30, 2017 was 21.1% and 20.6%, respectively, of gross OMIDRIA product sales. We expect our provision for chargebacks and rebates for the remainder of 2017 to remain relatively constant as a percentage of product sales with the quarter ended September 30, 2017.

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 as a reduction to revenue 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 to correlate generally with changes in product sales. If we have pass-through or similar reimbursement prior to January 1, 2018 or shortly thereafter, we expect our product return allowance to continue to correlate with product sales. If pass-through or similar reimbursement is not received by or shortly after January 1, 2018, our product return allowance will likely increase significantly during the fourth quarter of 2017 and the first quarter of 2018 and, as described above, our net sales will likely decrease significantly.

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.

[Table of Contents](#)

The following table illustrates our expenses associated with these activities:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Direct external expenses:				
Clinical research and development:				
MASP-2 Program - OMS721	\$ 6,480	\$ 4,845	\$ 13,935	\$ 13,826
OMIDRIA - Ophthalmology	436	505	2,848	3,279
Other clinical programs	22	141	111	546
Total clinical research and development	6,938	5,491	16,894	17,651
Preclinical research and development	1,438	318	3,011	1,224
Total direct external expenses	8,376	5,809	19,905	18,875
Internal, overhead and other expenses	5,162	5,527	16,273	14,752
Stock-based compensation expense	1,297	1,156	4,034	4,530
Total research and development expenses	\$ 14,835	\$ 12,492	\$ 40,212	\$ 38,157

The increase in direct external expenses for the three months ended September 30, 2017, compared to the same period in 2016 is due primarily to higher third-party manufacturing scale up costs for our OMS721 program as we continue to increase our production capacity to meet anticipated clinical and commercial requirements and higher third-party development expenses incurred as we continue to advance our preclinical and development drug candidates towards the clinic.

The increase in direct external expenses for the nine months ended September 30, 2017 compared to the nine months ended September 30, 2016 was due primarily to a larger number of drug products currently in preclinical stage research and development. This increase was mostly offset by the completion of a post-marketing OMIDRIA pediatric trial earlier this year, and decreased manufacturing costs associated with the product validation of OMIDRIA related to the transfer of our production to a new commercial manufacturing facility.

The changes in internal, overhead and other expenses is due to employee related costs and timing of employee bonuses.

We anticipate that total research and development costs will increase throughout the remainder of this year primarily due to Phase 3 clinical programs in IgA nephropathy and in HSCT-TMA, and accelerating our OMS721 manufacturing capabilities.

At this time, we are unable to estimate with any certainty the longer-term 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. 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 unable to estimate with any certainty when or if we would recognize any net cash inflows from our research and development projects.

[Table of Contents](#)*Selling, General and Administrative Expenses*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Selling, general and administrative expenses, excluding stock-based compensation expense	\$ 10,005	\$ 9,078	\$ 34,601	\$ 26,906
Stock-based compensation expense	1,744	1,379	5,415	5,036
Total selling, general and administrative expenses	\$ 11,749	\$ 10,457	\$ 40,016	\$ 31,942

The increase in selling, general and administrative expenses during the three and nine months ended September 30, 2017 compared to the same periods in 2016 was primarily due to increased legal costs associated with the Par lawsuit, which was resolved in October 2017, and to a lesser degree, increased employee costs. For more information regarding the conclusion of the Par lawsuit, see Part II, Item 1, "Legal Proceedings."

The increase in stock-based compensation expense during the three and nine months ended September 30, 2017 compared to the same periods in the prior year was due to additional sales and administrative employee option grants, and higher Black-Scholes valuation per share used to calculate period cost for certain of our options.

We anticipate selling, general and administrative costs will decrease during the remainder of this year due primarily to reduced legal costs in connection with enforcing our patents.

Interest Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Interest expense	\$ 2,780	\$ 2,135	\$ 8,166	\$ 5,367

The increase in interest expense during the three and nine months ended September 30, 2017 compared to the same period in the prior year was primarily due to the increase in our outstanding notes payable balance under the CRG Loan Agreement as compared to our notes payable balance with our former lender during the comparative periods.

Other Income, Net

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In thousands)		(In thousands)	
Other income, net	\$ 408	\$ 211	\$ 1,010	\$ 673

Other income, net principally includes sublease rental income and interest earned. The increase during the three and nine months ended September 30, 2017 is due to incremental subleased space as compared to the same periods in 2016.

[Table of Contents](#)

Financial Condition - Liquidity and Capital Resources

As of September 30, 2017, we had \$86.8 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 as compared to \$45.3 million at December 31, 2016. During the third quarter we raised \$63.6 million in a securities offering in which we sold 3.0 million shares of our common stock at a public offering price of \$22.75 per share.

Our notes payable and lease financing obligation increased to \$82.8 million as of September 30, 2017, compared to \$79.5 million as of December 31, 2016. The increase was due to the deferral of interest payments under our CRG Loan Agreement and entering into additional leases for equipment. In October 2017, we and CRG agreed to amend the CRG Loan Agreement. As such, we have the ability, at our sole discretion and subject to customary closing conditions, to borrow up to an additional \$45.0 million under the CRG Loan Agreement on or prior to March 21, 2018. For more information regarding the CRG Loan Agreement, see below under “*Loan and Security Agreement*” and under Part I, Note 7 - Notes Payable.

We have had a history of net losses and use of cash in operations (\$36.9 million and \$32.1 million, respectively, for the nine months ended September 30, 2017). As of September 30, 2017 we had \$86.8 million in cash, cash equivalents and short-term investments. In addition, we expect to collect the \$24.6 million of accounts receivable outstanding as of September 30, 2017 and have the ability, at our sole discretion and subject to only customary closing conditions, to borrow an additional \$45.0 million under the CRG Loan Agreement on or prior to March 21, 2018. We believe that our assets, together with these incremental sources of funds, are adequate to fund our future financial obligations as they become due through November 9, 2018 regardless of the outcome of the separate-payment status for Medicare patients treated with our commercial product, OMIDRIA. This CMS pass-through status is due to expire on January 1, 2018. Therefore, we have determined that the conditions that raised substantial doubt about our ability to meet our financial obligations as they become due that existed in prior interim periods do not currently exist. This derived result may change in the future based on changes in conditions and/or events impacting our liquidity.

We expect to continue to incur negative operating cash flows until such time as OMIDRIA product sales or other sources of revenue (e.g., corporate partnering or licensing) generate sufficient cash inflows to finance our operations and debt service requirements (which debt service will be at least \$6.8 million through November 9, 2018).

Our future plans include securing continued separate reimbursement (or equivalent reimbursement treatment) for OMIDRIA beyond the January 1, 2018 expiration of pass-through reimbursement, and/or continuing to grow OMIDRIA revenues. If we are unable to secure continued separate reimbursement (or equivalent reimbursement treatment) for OMIDRIA when used in Medicare patients beyond January 1, 2018, we expect that the per unit price we receive for OMIDRIA would likely be reduced eventually and our product revenue could be significantly impacted. We may seek additional funding sources for general working capital, which may include establishing corporate partnerships, establishing collaboration and licensing revenue agreements, and issuing public or private equity securities, including selling common stock through our At Market Issuance Sales Agreement, or the ATM Agreement, with JonesTrading Institutional Services LLC, or JonesTrading (see Note 9 for further detail). We also have the ability, at our election and subject to customary closing conditions, to borrow an additional \$45.0 million that is currently available under our existing CRG Loan Agreement through March 2018.

Cash Flow Data

	Nine Months Ended September 30,	
	2017	2016
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	\$ (32,055)	\$ (40,641)
Investing activities	(43,030)	(10,324)
Financing activities	73,887	59,897

Operating Activities. Net cash used in operating activities was \$32.1 million for the nine months ended September 30, 2017, a decrease of \$8.6 million from the same period in 2016. The cash used in operating activities was affected by our net loss of \$36.9 million, a \$12.5 million increase in accounts receivable and a \$3.9 million increase in prepaid expenses, partially offset by an \$8.1 million increase in accounts payable and accrued expenses, non-cash stock-based compensation expense of

[Table of Contents](#)

\$9.4 million, and non-cash interest expense of \$3.1 million. The increase in accounts receivable is directly related to increased OMIDRIA sales and the prepaid expense increase relates to advance payments and reservation fees for manufacturing of drug product for use in clinical trials.

Net cash used in operating activities was \$40.6 million for the same period in 2016 and was affected by our net loss of \$47.1 million, partially offset by stock-based compensation expense of \$9.6 million. An increase in accounts receivable of \$3.9 million and in OMIDRIA inventory of \$0.9 million also impacted net cash used in operating activities.

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

Net cash used in investing activities during the nine months ended September 30, 2017 was \$43.0 million, an increase of \$32.7 million from the same period in 2016. While we experienced a \$25.4 million decrease in proceeds from the sale and maturities of investments during the nine months ended September 30, 2017 compared to the same period in 2016, we also experienced a \$7.0 million increase in the purchases of short-term investments for the nine months ended September 30, 2017 as compared to the same period in 2016.

Financing Activities. Net cash provided by financing activities during the nine months ended September 30, 2017 was \$73.9 million, an increase of \$14.0 million compared to the same period in 2016. Net cash provided by financing activities for the nine months ended September 30, 2017 included \$63.6 million raised in a securities offering, and \$10.5 million from proceeds received from the exercise of stock options. During the same period in 2016, we raised \$38.0 million in a securities offering, received \$19.9 million from additional borrowings, and received \$2.2 million in proceeds from the exercise of stock options during the same period in 2016.

Loan and Security Agreement

In October 2016, we entered into the CRG Loan Agreement, pursuant to which we pledged substantially all of our assets, including intellectual property, as collateral. As of September 30, 2017, we had \$83.0 million outstanding under the CRG Loan Agreement. In October 2017, we and CRG amended the CRG Loan Agreement so that we will be permitted to borrow, at our sole discretion and subject to customary closing conditions, up to an additional \$45.0 million available through March 21, 2018. For more information regarding the CRG Loan Agreement, see below under “*Loan and Security Agreement*” and under Part I, Note 7 -Notes Payable.

The CRG Loan Agreement accrues interest at an annual rate of 12.25%, 4.00% of which can be deferred at our option until December 2020 by adding such amount to the aggregate principal amount. As of September 30, 2017 we have deferred \$3.0 million (\$2.5 million for the nine months ended September 30, 2017) of interest under the CRG Loan Agreement. The CRG Loan Agreement requires us to achieve certain annual minimum net revenue thresholds or minimum market capitalization thresholds. See Note 7 to our Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q.

At Market Issuance Sales Agreement

In January 2016, we entered into the ATM Agreement with JonesTrading. Pursuant to the ATM Agreement, we may direct JonesTrading to sell shares of our common stock with an aggregate offering price of up to \$50.0 million directly on The Nasdaq Global Market, through or to 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” (as defined in the ATM Agreement).

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, 2016 that was filed with the SEC on March 16, 2017. Other than the following, our future minimum contractual obligations and commitments have not changed materially from the amounts previously reported.

[Table of Contents](#)

Goods & Services

We have entered into an agreement with Hospira Worldwide, Inc., a wholly owned subsidiary of Pfizer, Inc., or Hospira, for the ongoing commercial supply of OMIDRIA and on November 1, 2017 submitted a supplemental new drug application, or sNDA, for the approval of Hospira as a manufacturing site for OMIDRIA. We expect that the Hospira facility will be approved for the production of OMIDRIA by the end of 2017. We do not anticipate any material delays in obtaining this approval and have adequate inventory on hand to meet expected demand. We have no firm purchase commitments outstanding related to commercial lots under this agreement as of September 30, 2017.

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 8 to our Consolidated Financial Statements for the year ended December 31, 2016 included in our Annual Report on Form 10-K, as filed with the SEC on March 16, 2017, 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 condensed consolidated financial statements:

- Revenue recognition;
- Research and development expenses, primarily clinical trial expenses and manufacturing of drug product and clinical drug supply; 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, 2016 that was filed with the SEC on March 16, 2017. 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, 2016.

Off-Balance Sheet Arrangements

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

[Table of Contents](#)

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is primarily confined to our investment securities and notes payable. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities. As of September 30, 2017, we had cash, cash equivalents and short-term investments of \$86.8 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These securities in our investment portfolio are not leveraged and are classified as available-for-sale. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the realized value of our investment portfolio. We actively monitor changes in interest rates and, with our current portfolio of short-term investments, we are not exposed to potential loss due to changes in interest rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2017. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2017, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the third quarter of 2017, we completed the implementation of several significant Enterprise Resource Planning System, or ERP, modules including core financial and purchasing modules. In connection with the implementation of the ERP system, we updated the processes that constitute our internal control over financial reporting to accommodate changes to our business processes and accounting procedures. Such processes will require testing for effectiveness; however, we do not believe that the implementation of the ERP system has had or will have a material adverse effect on our internal control over financial reporting.

Except as otherwise described above, there have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2017, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On October 4, 2017, we entered into a Settlement Agreement, or the Settlement Agreement, and consent judgment with Par, resolving our patent litigation against Par, which arose from Par's filing of an Abbreviated New Drug Application, or ANDA, seeking approval from the FDA to market a generic version of OMIDRIA. Pursuant to the Settlement Agreement, Par, which had previously stipulated to infringement, acknowledged and confirmed the validity of each of the patents listed in the Orange Book for OMIDRIA, which are U.S. Patent No. 8,173,707, U.S. Patent No. 8,586,633, U.S. Patent No. 9,066,856, U.S. Patent No. 9,278,101, U.S. Patent No. 9,399,040, and U.S. Patent No. 9,486,406.

In accordance with the terms of the Settlement Agreement, the U.S. District Court for the District of Delaware entered a consent judgment on October 5, 2017, pursuant to which Par and its affiliates are prohibited from launching a generic version of OMIDRIA until the earlier of April 1, 2032 or a date on which we or a third party, through licensing or any future final legal judgment, should one ever exist, with respect to our Orange Book listed patents, is able to launch a generic version of OMIDRIA, as further detailed in the Settlement Agreement (such date referred to as the Entry Date). Under the Settlement Agreement, we granted Par a non-exclusive, nonsublicensable license to make, sell and distribute a generic version of OMIDRIA between the Entry Date and the latest expiration of our U.S. patents related to OMIDRIA (*i.e.*, October 23, 2033). During this period, Par will pay to us a royalty equal to 15% of Par's net sales of its generic version of OMIDRIA.

In May 2017, we received Notice Letters from Sandoz and Lupin that each had filed an ANDA containing a Paragraph IV Certification under the Hatch-Waxman Act seeking approval from the FDA to market a generic version of OMIDRIA prior to the expiration of six Orange Book-listed patents covering OMIDRIA. On June 21, 2017, we filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware and a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Sandoz and on June 22, 2017 we filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware and a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Lupin. The Delaware lawsuits against Sandoz and Lupin were consolidated for all purposes by court order entered October 16, 2017, and the New Jersey lawsuits were dismissed by agreement of the parties on October 13, 2017. Sandoz has filed an answer to our Delaware lawsuit asserting defenses of patent invalidity. Lupin has filed an answer to our Delaware lawsuit asserting defenses and counterclaims for declaratory judgment of patent invalidity and non-infringement. The lawsuits were filed under the Hatch-Waxman Act for Sandoz's and Lupin's respective infringement of six Omeros patents: U.S. Patent Nos. 8,173,707, 8,586,633, 9,066,856, 9,278,101, 9,399,040 and 9,486,406, which relate to OMIDRIA and are listed in the Orange Book. These patents were granted following review by the U.S. Patent and Trademark Office, are presumed to be valid under governing law, and can only be invalidated in federal court with clear and convincing evidence. Under the Hatch-Waxman Act, we were permitted to file suit within 45 days from receipt of each Notice Letter and thereby trigger a 30-month stay of the FDA's approval of the respective ANDAs. Each stay is expected to remain in effect until November 2019 while the lawsuits are pending. The assertions raised in Sandoz's and Lupin's Paragraph IV Notice Letters and their answers to our lawsuits are substantially similar to those raised by Par in the above-described patent litigation matter against Par. We believe the assertions in the Sandoz and Lupin Paragraph IV Notice Letters and their answers to our lawsuits do not have merit, and we intend to vigorously prosecute our infringement claims against each of Sandoz and Lupin.

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, 2016.

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 September 30, 2017, we recorded net sales of OMIDRIA of \$21.7 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

[Table of Contents](#)

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 healthcare community;
- the extent of coverage and reimbursement for OMIDRIA when used in Medicare patients following the expiration of pass-through reimbursement effective January 1, 2018;
- 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 September 30, 2017, we had an accumulated deficit of approximately \$506.8 million. We expect to continue to spend substantial amounts to:

- continue OMIDRIA sales and marketing;
- continue research and development in our programs;
- make principal, interest and fee payments under the CRG 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

[Table of Contents](#)

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 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.

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 potential other commercialized products, our prospects for revenue and profitability would suffer.

Our 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 for any product from each government or third-party payer can be a time-consuming and costly process that may require expansion of staff and/or increased use 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, OMS103 or any of our product candidates, or to surgeons for the administration and delivery of these products or product candidates will be considered adequate to justify the use of these products or product candidates. 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. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. Pricing may also be adversely affected by changes in the terms, scope and/or complexity of government pricing requirements.

Even if we achieve 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 when used in Medicare patients. In November 2017, CMS issued its 2018 Hospital Outpatient Prospective Payment System Final Rule, effective January 1, 2018, under which OMIDRIA would no longer have separate payment under Medicare Part B and consequently would be included as part of the packaged procedural payment when used in cataract surgery in Medicare patients. In the event that separate or similar reimbursement is not obtained for OMIDRIA after that date and/or the pass-through period is not extended, we expect that OMIDRIA will be included as part of the packaged payment. If that occurs, we expect that the per unit price we receive for OMIDRIA would likely be reduced, possibly substantially, which may reduce our net revenues depending on the volume of units sold. Further, OMIDRIA end user customers may defer purchases of OMIDRIA during the latter part of 2017, and particularly during the fourth quarter of 2017, if the reimbursement status of the product after December 31, 2017 is uncertain. If customers defer purchases of OMIDRIA, our revenues for the applicable period would be reduced, potentially by a significant amount. In addition, if the rate at which OMIDRIA is reimbursed after December 31, 2017 is less than we expect, we may be required to provide a credit to customers who purchased but did not use the product in 2017, which would result in a reduction of our net product sales, potentially by a

[Table of Contents](#)

significant amount. An extension or separate reimbursement for OMIDRIA requires action from legislative and/or administrative authorities and, as a consequence, we cannot guarantee that any such action will be taken or, if taken, when such action will be effective, nor can we predict the actual reimbursement rate.

In non-U.S. jurisdictions, we must obtain separate reimbursement approvals and comply with related foreign legal and regulatory requirements. In some countries, including those in the EU, our products may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time and expenditure of resources after the receipt of marketing approval for a product. We provide no assurances that the price of any product in one or more of these countries or regions will allow us to make a profit or cover our costs, including research, development, manufacturing, sales and distribution, and as a result we may decide to delay, potentially indefinitely, initiating sales in the particular country or region.

If the reimbursement or pricing that we are able to obtain and maintain for any product that we develop and commercialize, including OMIDRIA, is inadequate, is significantly delayed or is subject to overly restrictive conditions, our ability to generate revenue, attain profitability and/or commercialize our product candidates may be impaired and there could be a material adverse effect on our business, financial condition, results of operations and growth prospects and the trading price of our stock could decline.

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 the design of our clinical trials as actually run or 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. We are required to comply with other post-marketing requirements including GMPs, advertising and promotion restrictions, reporting and recordkeeping obligations and other requirements. 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 and, in particular, laws (such as the Anti-Kickback Statute, the False Claims Act and the Sunshine Act) applicable when drug products are purchased or reimbursed by a federal healthcare program. 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 and maintaining an effective compliance program requires the expenditure of significant time and

[Table of Contents](#)

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.

We may face difficulties from changes to current regulations as well as future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

There is uncertainty with respect to the impact that health care reform legislation may have on coverage and reimbursement for healthcare items and services covered by plans that are authorized by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA. In this regard, President Trump and various members of Congress have expressed a desire to repeal all or portions of the ACA. President Trump has also made statements about controlling drug prices. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact that such legislation may have on us.

We expect that the ACA, if it remains in effect, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate sufficient revenue, attain and/or maintain profitability or commercialize our product candidates. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on OMIDRIA or the marketing approvals of our product candidates, if any, may be.

Failure to obtain and maintain 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 EMA does not ensure approval by regulatory agencies in other jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. 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. In addition, even if we were able to obtain regulatory approval for a product in one or more foreign jurisdictions, we may need to complete additional requirements to maintain that approval and our ability to market the product in the applicable jurisdiction. For example, OMIDRIA must be placed on the market (*i.e.*, released into the distribution chain) in at least one EEA country by July 28, 2018 in order for our EU marketing authorization for OMIDRIA to remain valid.

OMIDRIA, as well as any of our product candidates, if approved, that are marketed outside of the United States, may face a variety of risks associated with international operations that, if realized, could materially adversely affect our business.

We may be subject to additional risks for OMIDRIA or any of our product candidates that 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 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.

[Table of Contents](#)

Any of these risks, if realized, could increase our operating expenses and reduce our revenues.

We have no internal capacity to manufacture commercial or clinical 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 and supplying 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, manufacturing, supply chain and/or release 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 certain of our programs, including but not limited to MASP-2 and MASP-3, 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 a sufficient number of them on commercially reasonable terms, if at all.

Any significant delays in the manufacture and/or supply 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. An sNDA was submitted in November 2017 for the approval of Hospira as a manufacturing site for OMIDRIA, but approval by the FDA or other regulatory agencies of Hospira as a manufacturing site has not been completed. We do not presently have an alternate manufacturing facility for OMIDRIA in operation. 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 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/or other raw materials plus primary and secondary packaging materials necessary for our contract manufacturers to produce OMIDRIA and our 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 product candidates, we have not yet entered into agreements for the supply of all such ingredients,

[Table of Contents](#)

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, failure to deliver an efficacious dose of a product candidate, 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; or
- 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.

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;
- inability to deliver an efficacious dose of a product candidate; 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.

[Table of Contents](#)

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 have limited 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.

Our preclinical programs may not produce product candidates that are suitable for clinical trials, our product candidates may not successfully complete clinical development and/or our product candidates may not be suitable for successful commercialization or generation of 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 product candidates do not successfully complete preclinical testing. There can be no assurance that positive results from preclinical studies will be predictive of results obtained from subsequent preclinical studies or clinical trials. Even if preclinical testing is successfully completed, we 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 may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and such costs or an adverse outcome in such a proceeding may have a material negative effect on our financial condition, results of operations and/or stock price.

If we choose to go to court or take other enforcement action to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that our 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 our patents. In addition, a lawsuit 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. 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 any 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 patent infringement lawsuits against Sandoz and Lupin.

[Table of Contents](#)

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

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

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

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.

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;

Table of Contents

- 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.

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 \$80.0 million under the CRG Loan Agreement and pledged substantially all of our assets, including intellectual property, as collateral. The CRG 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 cash dividends or make distributions, repurchase stock, license certain of our intellectual property on an exclusive basis 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 CRG Loan Agreement requires us to achieve either (a) certain minimum net revenue amounts from OMIDRIA through the end of 2021, which are \$55.0 million and \$65.0 million for the 2017 and 2018 calendar years, respectively, or (b) a minimum market capitalization threshold equal to the product of 6.4 multiplied by the aggregate principal amount of loans outstanding under the CRG Loan Agreement determined as of the fifth business day following announcement of earnings results for the applicable year. In the event we do not achieve either of the minimum revenue amount or the minimum market capitalization threshold for a year, we can satisfy the requirement by raising additional funds through an equity or subordinated debt issuance and using the proceeds to pay down the loan balance by an amount equal to the difference between the minimum revenue amount for such year and the actual revenue amount for such year. We recorded net sales of OMIDRIA of \$51.1 million for the nine-month period ended September 30, 2017, and we cannot provide assurance that we will generate sufficient revenue from OMIDRIA in the future to satisfy fully the net revenue covenants in 2017 and/or subsequent years during the term of the CRG Loan Agreement. We are also required to maintain \$5.0 million in cash and cash equivalents during the term of the CRG Loan Agreement.

The failure to satisfy these or other obligations under the CRG Loan Agreement would constitute an event of default. An event of default under the CRG Loan Agreement also includes the occurrence of any material adverse effect upon our business, condition (financial or otherwise), operations, performance or property taken as a whole. If there is an event of default under the CRG Loan Agreement, the lenders may have the right to accelerate all of our repayment obligations under the CRG Loan Agreement and to take control of our pledged assets, which include substantially all of our assets including our intellectual property. 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.

Under the CRG Loan Agreement, we may borrow up to an additional \$45.0 million on or before March 21, 2018, subject to customary closing conditions including but not limited to the lack of a default under the CRG Loan Agreement or the lack of the occurrence of material adverse change in or on the business, condition (financial or otherwise), operations, performance or property of Omeros and its subsidiaries taken as a whole. If we are unable to satisfy each of these conditions, we will not be able to borrow any of the additional \$45.0 million and it may be necessary for us to seek alternative sources of capital.

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

[Table of Contents](#)

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 believe that it is unlikely they will do so. We continue to evaluate 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 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 OMS103 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 OMS103 or any other future product that we may market to compete effectively 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. Demopoulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, 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.

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.

[Table of Contents](#)

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 for OMIDRIA or for our product candidates, if commercialization 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.

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), 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 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, or if we do not meet diligence or other obligations under the corresponding licenses, we may not be able to commercialize product candidates from these programs.

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.

[Table of Contents](#)

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-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 September 30, 2017, our stock traded as high as \$27.09 per share and as low as \$7.20 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 9.9 million shares of common stock as of September 30, 2017 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 September 30, 2017 we also had approximately 3.5 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.

[Table of Contents](#)

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 CRG Loan Agreement, we have agreed not to pay any cash 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.

Table of Contents

ITEM 6. EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
10.1(1)	<u>Settlement Agreement, dated October 4, 2017, by and among Omeros Corporation, Par Sterile Products, LLC and Par Pharmaceutical, Inc.</u>
10.2(2)	<u>Amendment No. 1 to Loan Agreement among Omeros Corporation, CRG Servicing LLC, as administrative agent and collateral agent, and the lenders named therein, dated October 11, 2017</u>
12.1	<u>Ratio of Earnings to Fixed Charges</u>
31.1	<u>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</u>
31.2	<u>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</u>
32.1	<u>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</u>
32.2	<u>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</u>
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 10.1 of the registrant's Current Report on Form 8-K filed on October 5, 2017 (File No. 001-34475).

(2) Incorporated by reference to Exhibit 10.1 of the registrant's Current Report on Form 8-K filed on October 17, 2017 (File No. 001-34475).

[Table of Contents](#)

SIGNATURES

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

OMEROS CORPORATION

Dated: November 9, 2017

/s/ Gregory A. Demopulos

Gregory A. Demopulos, M.D.

President, Chief Executive Officer and Chairman of the Board of Directors

Dated: November 9, 2017

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Vice President, Finance, Chief Accounting Officer and Treasurer

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

	For the nine months ended			Year Ended December 31,		
	2017	2016	2015	2014	2013	2012
	(in thousands)			(in thousands)		
Earnings before fixed charges:						
Loss from continuing operations before income taxes	\$ (36,930)	\$ (66,745)	\$ (75,096)	\$ (73,673)	\$ (39,796)	\$ (38,444)
Add fixed charges	10,813	16,697	8,295	6,824	5,621	2,305
Add amortization of capitalized interest	—	—	—	—	—	—
Add distributed income of equity investees	—	—	—	—	—	—
Subtract capitalized interest	—	—	—	—	—	—
Loss before fixed charges	<u>\$ (26,117)</u>	<u>\$ (50,048)</u>	<u>\$ (66,801)</u>	<u>\$ (66,849)</u>	<u>\$ (34,175)</u>	<u>\$ (36,139)</u>
Fixed Charges:						
Interest expense	\$ 7,578	\$ 6,359	\$ 2,709	\$ 2,710	\$ 1,865	\$ 1,355
Amortization of debt expense and loss from extinguishment of debt	588	7,055	2,177	759	502	374
Estimate of interest expense within rental expense	2,647	3,283	3,409	3,355	3,254	576
Preference security dividend requirements of consolidated subsidiaries	—	—	—	—	—	—
Total fixed charges	<u>\$ 10,813</u>	<u>\$ 16,697</u>	<u>\$ 8,295</u>	<u>\$ 6,824</u>	<u>\$ 5,621</u>	<u>\$ 2,305</u>
Deficiency of earnings available to cover fixed charges	\$ (36,930)	\$ (66,745)	\$ (75,096)	\$ (73,673)	\$ (39,796)	\$ (38,444)

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

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

1. I have reviewed this quarterly report on Form 10-Q of Omeros Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 9, 2017

/s/ Gregory A. Demopoulos

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

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

I, Michael A. Jacobsen, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Omeros Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 9, 2017

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Omeros Corporation (the "Company") for the quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

Dated: November 9, 2017

/s/ Gregory A. Demopoulos

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

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Omeros Corporation (the "Company") for the quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

Dated: November 9, 2017

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Principal Financial and Accounting Officer

