OMEROS CORP

Form 10-O

November 09, 2016

Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF $^{\rm X}$ 1934

For the quarterly period ended September 30, 2016

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

For the transition period from to

Commission file number: 001-34475

OMEROS CORPORATION

(Exact name of registrant as specified in its charter)

Washington 91-1663741 (State or other jurisdiction of (I.R.S. Employer incorporation or organization) Identification Number)

201 Elliott Avenue West

Seattle, Washington

98119

(Address of principal executive offices) (Zip Code)

(206) 676-5000

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer "

Accelerated filer

Non-accelerated filer "(Do not check if a smaller reporting company) Smaller reporting company " Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No x

As of November 2, 2016, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 42,915,928.

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

our plans for sales, marketing and distribution of OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3%; our expectations regarding our product sales and our estimate regarding how long our existing cash, cash equivalents, short-term investments and revenues will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes under our Term Loan Agreement with CRG Servicing LLC and the lenders identified therein;

our ability to raise additional capital through the capital markets, including under our at-the-market equity facility with JonesTrading Institutional Services LLC, or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;

• our ability to forecast accurately wholesaler demand as well as our estimates of chargebacks and rebates, distribution fees and estimated product returns;

our expectations regarding the clinical, therapeutic and competitive benefits of OMIDRIA and our product candidates; our ability to design and successfully complete clinical trials and other studies for our products and product candidates and our plans and expectations regarding our clinical trials, including our clinical trials for OMS721 and for OMS824; our anticipation that we will rely on contract manufacturers to manufacture OMIDRIA for commercial sale and to manufacture our product candidates and our expectations regarding product supply and manufacturing of OMIDRIA; our ability to enter into acceptable arrangements with potential corporate partners, including with respect to OMIDRIA;

our expectations about the commercial competition that OMIDRIA and our product candidates, if commercialized, face or may face;

our expectation that the OMIDRIAssureTM Reimbursement Services Program will increase patient access to OMIDRIA; the extent of protection that our patents provide and that our pending patent applications will provide, if patents issue from such applications, for our technologies, programs, products and product candidates;

when or whether the dosing limitations in our OMS824 program may be removed;

in our OMS721 program, whether enrollment in a Phase 3 clinical trial in patients with atypical hemolytic uremic syndrome, or aHUS, opens in 2016, or 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, for indications for which we are pursuing such approval or designation;

the expected course and costs of existing claims, legal proceedings and administrative actions, our involvement in potential claims, legal proceedings and administrative actions, and the potential outcomes and effects of both existing and potential claims, legal proceedings and administrative actions, as well as regulatory determinations, on our business, prospects, financial condition and results of operations;

our expectations regarding our OMS103 exclusive license agreement including, without limitation, the manufacturing and commercialization of OMS103 and the commencement and subsequent continuation of product sales on which we could receive royalty revenue; and

our expected financial position, performance, revenues, growth, costs and expenses, magnitude of net losses and the availability of resources.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part II of this Quarterly Report on Form 10-Q under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results

of Operations" and in our other filings with the Securities and Exchange Commission, or SEC. Given these risks, uncertainties and other factors, actual results or anticipated developments may not be realized or, even if substantially realized, may not have the

Table of Contents

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, 2016 INDEX

	Page
Part I — Financial Information	<u>3</u>
Item 1. Financial Statements (unaudited)	<u>3</u>
Condensed Consolidated Balance Sheets	<u>3</u>
Condensed Consolidated Statements of Operations and Comprehensive Loss	<u>4</u>
Condensed Consolidated Statements of Cash Flows	<u>5</u>
Notes to Condensed Consolidated Financial Statements	<u>6</u>
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>13</u>
Item 3. Quantitative and Qualitative Disclosures About Market Risk	<u>22</u>
Item 4. Controls and Procedures	<u>22</u>
Part II — Other Information	<u>23</u>
Legal Proceedings	<u>23</u>
Item 1A. Risk Factors	<u>23</u>
Item 6. Exhibits	<u>36</u>
<u>Signatures</u>	<u>37</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)

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	September 30, December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,297	\$ 1,365
Short-term investments	37,144	26,898
Receivables	10,457	6,517
Inventory	1,396	472
Prepaid expense	1,355	1,894
Total current assets	60,649	37,146
Property and equipment, net	1,206	951
Restricted cash and investments	10,835	10,679
Other assets	73	219
Total assets	\$ 72,763	\$ 48,995
Liabilities and shareholders' deficit		
Current liabilities:	Φ 2 005	Φ 6 400
Accounts payable	\$ 3,985	\$ 6,428
Accrued expenses	11,882	9,752
Current portion of notes payable	190	73
Total current liabilities	16,057	16,253
Notes payable, net of current portion	70,289	49,769
Deferred rent	9,189	9,207
Commitments and contingencies (Note 8)		
Shareholders' deficit:		
Preferred stock, par value \$0.01 per share, 20,000,000 shares authorized and none issued		
and outstanding at September 30, 2016 and December 31, 2015		
Common stock, par value \$0.01 per share, 150,000,000 shares authorized at September	420	200
30, 2016 and December 31, 2015; 42,910,489 and 38,040,891 issued and outstanding at	429	380
September 30, 2016 and December 31, 2015, respectively	407.054	276.520
Additional paid-in capital	427,054	376,528
Accumulated deficit	(450,255) (403,142)
Total shareholders' deficit	(22,772) (26,234)
Total liabilities and shareholders' deficit	\$ 72,763	\$ 48,995
See notes to condensed consolidated financial statements		

Table of Contents

OMEROS CORPORATION

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Revenues				
Product sales, net	\$11,289	\$3,244	\$28,539	\$6,607
Grant revenue	_	15	173	227
Total revenue	11,289	3,259	28,712	6,834
Costs and expenses				
Cost of product sales	378	248	1,032	624
Research and development	12,492	13,264	38,157	33,482
Selling, general and administrative	10,457	9,048	31,942	25,926
Total costs and expenses	23,327	22,560	71,131	60,032
Loss from operations	(12,038)	(19,301)	(42,419)	(53,198)
Interest expense	(2,135)	(871)	(5,367)	(2,765)
Other income (expense), net	211	251	673	693
Net loss	\$(13,962)	\$(19,921)	\$	