OMEROS CORP
Form 10-Q
August 08, 2017
Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2017

or

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

For the transition period from to

Commission file number: 001-34475

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

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

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

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

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 o

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	o	Accelerated filer	x
Non-accelerated filer	o (Do not check if a smaller reporting company)	Smaller reporting company	o
Emerging growth company	o		

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. o

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

As of August 4, 2017, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 44,803,848.

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," "shoul similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

- our plans for sales, marketing and distribution of OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3%;
- our expectations regarding our product sales and our estimate regarding how long our existing cash, cash equivalents, short-term investments and revenues will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes under our Term Loan Agreement, or the CRG Loan Agreement, with CRG Servicing LLC, or CRG, 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 JonesTrading, or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;
- our ability to obtain separate or similar reimbursement for OMIDRIA beyond January 1, 2018 and/or to extend the pass-through period, our expectations that OMIDRIA would be part of the packaged payment in the event that we do not obtain separate or similar reimbursement for OMIDRIA, and our expectations regarding the per unit price we will receive for OMIDRIA in the future;
- 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 Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC, which we refer to collectively as Par, and against Sandoz, Inc., or Sandoz, and against Lupin Ltd. and Lupin Pharmaceuticals, which we refer to collectively as Lupin;
- 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, for OMS824 and for OMS527;
- in our OMS721 program, whether enrollment in a Phase 3 clinical trial in patients with atypical hemolytic uremic syndrome, or aHUS, will proceed as expected; 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, or whether 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;
- 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 expectations about the commercial competition that OMIDRIA and our product candidates, if commercialized, face or may face;
- our expectation that the OMIDRIAssure® Reimbursement Services Program will 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

- our expectations regarding our OMS103 exclusive license agreement including, without limitation, manufacturing and commercialization of OMS103 and the commencement and subsequent continuation of product sales on which we could receive royalty revenue;
- 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; and
- our expected financial position, performance, revenues, growth, costs and expenses, magnitude of net losses and the availability of resources.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part II of this Quarterly Report on Form 10-Q under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in our other filings with the Securities and Exchange Commission, or SEC. Given these risks, uncertainties and other factors, actual results or anticipated developments may not be realized or, even if substantially realized, may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements, which represent our estimates and assumptions only as of the date of the filing of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable 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 June 30, 2017
INDEX

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)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$3,386	$ 2,224
Short-term investments	26,281	43,107
Receivables	19,075	12,037
Inventory	905	1,128
Prepaid expense	3,446	1,766
Total current assets	53,093	60,262
Property and equipment, net	1,426	1,181
Restricted cash and investments	5,835	5,835
Total assets	$60,354	$ 67,278
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$2,572	$ 2,519
Accrued expenses	21,643	13,252
Current portion of deferred rent	288	102
Current portion of lease financing obligations	250	198
Total current liabilities	24,753	16,071
Notes payable and lease financing obligations, net	81,511	79,512
Deferred rent	8,940	9,142
Commitments and contingencies (Note 8)		
Shareholders' deficit:		
Preferred stock, par value $0.01 per share, 20,000,000 shares authorized and none issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock, par value $0.01 per share, 150,000,000 shares authorized at June 30, 2017 and December 31, 2016; 44,447,603 and 43,819,133 issued and outstanding at June 30, 2017 and December 31, 2016, respectively	444	438
Additional paid-in capital	444,041	432,002
Accumulated deficit	(499,335)	(469,887)
Total shareholders' deficit	(54,850)	(37,447)
Total liabilities and shareholders' deficit	$60,354	$ 67,278

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues				
Product sales, net	$17,151	$10,004	$29,408	$17,250
Grant revenue	—	—	—	173
Total revenue	17,151	10,004	29,408	17,423
Costs and expenses				
Cost of product sales	157	327	429	654
Research and development	13,137	10,231	25,377	25,665
Selling, general and administrative	15,796	10,375	28,267	21,485
Total costs and expenses	29,090	20,933	54,073	47,804
Loss from operations	(11,939)	(10,929)	(24,665)	(30,381)
Interest expense	(2,723)	(1,857)	(5,386)	(3,232)
Other income (expense), net	303	174	603	462
Net loss	$(14,359)	$(12,612)	$(29,448)	$(33,151)
Comprehensive loss	$(14,359)	$(12,612)	$(29,448)	$(33,151)
Basic and diluted net loss per share	$(0.33)	$(0.32)	$(0.67)	$(0.86)
Weighted-average shares used to compute basic and diluted net loss per share	44,037,471	39,178,547	43,933,022	38,747,816

See notes to condensed consolidated financial statements

Table of Contents

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

	Six Months Ended June 30,	
	2017	2016
Operating activities:		
Net loss	$(29,448)	$(33,151)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	234	122
Stock-based compensation expense	6,408	7,031
Non-cash interest expense	2,012	684
Changes in operating assets and liabilities:		
Receivables	(7,038)	(2,289)
Inventory	223	(1,308)
Prepaid expenses and other assets	(1,680)	(242)
Accounts payable, accrued expenses, and deferred rent	8,428	(270)
Net cash used in operating activities	(20,861)	(29,423)
Investing activities:		
Purchases of property and equipment	(316)	(34)
Purchases of investments	(1,102)	(20,625)
Proceeds from the sale and maturities of investments	17,928	30,875
Net cash provided by investing activities	16,510	10,216
Financing activities:		
Proceeds from issuance of common stock	—	724
Proceeds from borrowings under notes payable	—	19,864
Payments on notes payable and lease financing obligations	(124)	(34)
Proceeds upon exercise of stock options and warrants	5,637	1,877
Net cash provided by financing activities	5,513	22,431
Net increase in cash and cash equivalents	1,162	3,224
Cash and cash equivalents at beginning of period	2,224	1,365
Cash and cash equivalents at end of period	$3,386	$4,589
Supplemental cash flow information		
Cash paid for interest	$3,372	$2,005
Conversion of accrued interest to notes payable	$1,628	$—
Property acquired under capital lease	$163	$388
Issuance of warrants in connection with amendment to notes payable	$—	$758

See notes to condensed consolidated financial statements

Table of Contents

OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a 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 June 30, 2017 and for the three and six months ended June 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.

Going Concern

We have the responsibility to evaluate, based on the provisions of the Financial Accounting Standards Board (FASB) Accounting Standards Update (ASU) No. 2014-15, Presentation of Financial Statements - Going Concern (ASU 2014-15), whether conditions and/or events raise substantial doubt about our ability to meet our future financial obligations as they become due within one year after the date that these financial statements are issued. Our initial step in the evaluation does not take into consideration the potential mitigating effects of our plans that have not been fully implemented as of the date the financial statements are issued (e.g., continuing to grow revenues from the sales of OMIDRIA, establishing corporate partnerships or licensing agreements, future available debt financing, etc.)

In performing the first step of this assessment, the derived result is that the following conditions raise substantial doubt about our ability to meet our financial obligations as they become due. We have a history of net losses ($66.7 million in 2016 and $29.4 million for the six months ended June 30, 2017) and use significant cash in operating activities ($51.5 million in 2016 and $20.9 million for the six months ended June 30, 2017). As of June 30, 2017, we had $29.7 million in cash, cash equivalents and short-term investments available to fund operations and debt service costs. We expect to continue to incur negative 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 August 8, 2018). In addition, we also considered that pass-through reimbursement for our commercial product, OMIDRIA, is currently due to expire as of January 1, 2018 if we do not secure similar or separate reimbursement prior to that time.

In performing the second step of this assessment, we are required to evaluate under ASU 2014-15 whether our plans to mitigate the conditions above alleviate the substantial doubt about our ability to meet our obligations as they become due within one year after the date that these financial statements are issued. 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, and additional funding sources may include establishing corporate partnerships, establishing collaboration and licensing revenue agreements,

sale of assets, and issuing public or private equity securities, including selling common stock through our At Market Issuance Sales Agreement (ATM Agreement) with JonesTrading Institutional Services LLC (JonesTrading) (see Note 9 for further detail). We also have the ability, at our election, to borrow an additional $25.0 million that is currently available under our existing CRG Loan Agreement through September 2017. In addition, under the CRG Loan Agreement we have the ability to borrow an additional $20.0 million beyond the above-

Table of Contents

noted $25.0 million if our OMIDRIA net product sales exceed $25.0 million or if our average market capitalization averages at least $1.0 billion for any consecutive three-month period on or prior to December 31, 2017 (see Note 7 for further detail).

While an additional $25.0 million is currently available at our election under the CRG Loan Agreement and an additional $20.0 million may become available, the other sources of working capital are not currently assured, and consequently these sources of capital may not sufficiently mitigate the risks and uncertainties disclosed above. We have therefore concluded, based on the provisions of ASU 2014-15, that there is substantial doubt about our ability to continue as a going concern through August 8, 2018.

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

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 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 most recent of which was issued in December 2016. The effective date of the guidance requires us to adopt the standard at the beginning of our first quarter of fiscal 2018 with earlier application permitted. The new guidance requires either a modified retrospective method or a full retrospective method of transition. We currently anticipate adopting the guidance at the beginning of our first quarter of fiscal 2018 under the modified retrospective method. We currently do not anticipate a material impact on our revenue recognition practices. We continue to review variable consideration, potential disclosures, and our method of adoption to complete our evaluation of the impact on our consolidated financial statements. In addition, we continue to monitor additional changes, modifications, clarifications or interpretations undertaken by the FASB, which may impact our current conclusions.

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. We are evaluating how this new standard will impact the presentation of our financial

statements and related disclosures.

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.

Table of Contents

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 six months ended June 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:

	June 30,	
	2017	2016
Outstanding options to purchase common stock	10,334,730	9,501,818
Outstanding warrants to purchase common stock	100,602	100,602
Total	10,435,332	9,602,420

Note 3—Cash, Cash Equivalents and Investments

As of June 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;

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:

	June 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	26,281	—	—	26,281
Total	$32,116	$—	—$	—$32,116

	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	$48,942	$—	—$	—$48,942

Table of Contents

Cash held in demand deposit accounts of $3.4 million and $2.2 million is excluded from our fair-value hierarchy disclosure as of June 30, 2017 and December 31, 2016, respectively. There were no unrealized gains or losses associated with our short-term investments as of June 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:

June 30, 2017	December 31, 2016