

OMEROS CORP
 Form 10-Q
 August 10, 2015
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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 June 30, 2015

or

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

For the transition period from _____ to _____

Commission file number: 001-34475

OMEROS CORPORATION

(Exact name of registrant as specified in its charter)

Washington

(State or other jurisdiction of incorporation or organization)

91-1663741

(I.R.S. Employer Identification Number)

201 Elliott Avenue West

Seattle, Washington

(Address of principal executive offices)

(206) 676-5000

(Registrant's telephone number, including area code)

98119

(Zip Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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, 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 | <input type="checkbox"/> | Accelerated filer | <input checked="" type="checkbox"/> |
| Non-accelerated filer | <input type="checkbox"/> | Smaller reporting company | <input type="checkbox"/> |

(Do not check if a smaller reporting company)

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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 August 5, 2015, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 37,885,698.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act, which are subject to the “safe harbor” created by those sections for such statements. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. All statements other than statements of historical fact are “forward-looking statements.” Terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” 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% in the U.S. and for sales, marketing and distribution in the European Union and other international territories;
- our ability to forecast accurately wholesaler demand as well as our estimates of charge-backs and rebates, distribution fees and estimated product returns;
- our ability to enter into acceptable arrangements with potential corporate partners, including with respect to Omidria;
- our expectations regarding the clinical, therapeutic and competitive benefits of Omidria and our product candidates;
- our revenues and our estimate regarding how long our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes;
- our expectations regarding our exclusive license agreement related to OMS103 including, without limitation, the ability of our partner to manufacture and commercialize OMS103 and the commencement and subsequent continuation of product sales on which we will receive royalty revenue;
- our ability to raise additional capital through the capital markets or through one or more corporate partnerships, equity offerings, debt financings, collaboration or licensing arrangements or asset sales;
- our anticipation that we will rely on contract manufacturers to manufacture Omidria for commercial sale and develop and manufacture our product candidates;
- our expectations about the commercial competition that Omidria and our product candidates may face;
- our expectation that a patient assistance program and a commercial copay program will increase patient accessibility 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;
- our ability to design and successfully complete clinical trials and other studies for our products and product candidates, including our Phase 2 clinical trials for OMS721 and OMS824;
- our ability to recommence active enrollment in our Phase 2 clinical trial of OMS824 in Huntington’s disease or initiate further clinical studies in either our OMS824 Huntington’s or schizophrenia programs;
- our expected financial position, performance, growth, expenses, magnitude of net losses and availability of resources; and
- our estimates regarding our future net losses, revenues, research and development expenses and selling, general and administrative expenses.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part II of this Quarterly Report on Form 10-Q under 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 developments anticipated may not be realized or, even if substantially realized, they 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, including the securities laws of

the United States and the rules and regulations of the SEC, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

OMEROS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(unaudited)

| | June 30, 2015 | December 31, 2014 |
|---|------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$2,561 | \$ 354 |
| Short-term investments | 48,885 | 6,532 |
| Receivables | 3,071 | 392 |
| Inventory | 633 | 568 |
| Prepaid expense | 1,423 | 1,191 |
| Other current assets | 108 | 120 |
| Total current assets | 56,681 | 9,157 |
| Property and equipment, net | 789 | 782 |
| Restricted cash | 679 | 679 |
| Other assets | 488 | 472 |
| Total assets | \$58,637 | \$ 11,090 |
| Liabilities and shareholders' equity (deficit) | | |
| Current liabilities: | | |
| Accounts payable | \$4,045 | \$ 4,915 |
| Accrued expenses | 6,757 | 7,070 |
| Current portion of notes payable, net of discount | 9,294 | 6,446 |
| Total current liabilities | 20,096 | 18,431 |
| Notes payable, net of current portion and discount | 21,477 | 26,263 |
| Deferred rent | 9,132 | 9,050 |
| Commitments and contingencies (Note 7) | | |
| Shareholders' equity: | | |
| Preferred stock, par value \$0.01 per share, 20,000,000 authorized; none issued and outstanding at June 30, 2015 and December 31, 2014 | — | — |
| Common stock, par value \$0.01 per share, 150,000,000 authorized; 37,875,933 and 34,185,464 issued and outstanding at June 30, 2015 and December 31, 2014, respectively | 379 | 342 |
| Additional paid-in capital | 370,948 | 285,050 |
| Accumulated deficit | (363,395) | (328,046) |
| Total shareholders' equity (deficit) | 7,932 | (42,654) |
| Total liabilities and shareholders' equity | \$58,637 | \$ 11,090 |
| See notes to consolidated financial statements | | |

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OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

| | Three Months Ended | | Six Months Ended | |
|---|--------------------|-------------|------------------|-----------|
| | June 30, | | June 30, | |
| | 2015 | 2014 | 2015 | 2014 |
| Revenues | | | | |
| Product sales, net | \$3,125 | \$— | \$3,363 | \$— |
| Grant revenue | 62 | 45 | 212 | 145 |
| Total revenue | 3,187 | 45 | 3,575 | 145 |
| Costs and expenses: | | | | |
| Cost of product sales | 365 | — | 376 | — |
| Research and development | 10,900 | 12,407 | 20,218 | 24,424 |
| Selling, general and administrative | 7,889 | 4,855 | 16,878 | 8,622 |
| Total costs and expenses | 19,154 | 17,262 | 37,472 | 33,046 |
| Loss from operations | (15,967) | (17,217) | (33,897) | (32,901) |
| Interest expense | (937) | (939) | (1,894) | (1,611) |
| Investment income and other income (expense), net | 224 | 165 | 442 | (121) |
| Net loss | \$(16,680) | \$(17,991) | | |