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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 14, 2019

OMEROS CORPORATION

(Exact name of Registrant as Specified in Its Charter)

Washington
(State or Other Jurisdiction
of Incorporation)

001-34475
(Commission File Number)

91-1663741
(IRS Employer
Identification No.)

**201 Elliott Avenue West
Seattle, WA**
(Address of Principal Executive Offices)

98119
(Zip Code)

Registrant's Telephone Number, Including Area Code: (206) 676-5000

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On January 14, 2019, Omeros Corporation issued a press release announcing preliminary revenue results for the fourth quarter ended December 31, 2018. A copy of such press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the United States Securities and Exchange Commission made by Omeros Corporation, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	<u>Press release, dated January 14, 2019, pertaining to Omeros Corporation’s preliminary revenue results for the quarter ended December 31, 2018.</u>

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 hereunto duly authorized.

OMEROS CORPORATION

Date: January 14, 2019

By: /s/ Gregory A. Demopulos

Gregory A. Demopulos, M.D.
President, Chief Executive Officer and
Chairman of the Board of Directors



Omeros Corporation Announces Record High Quarterly Revenue Results for the Fourth Quarter 2018

– Broadening OMIDRIA Coverage from Payers and Increasing Funding for OMS721 Commercial Preparations –

SEATTLE, WA – January 14, 2019 – Omeros Corporation (Nasdaq: OMER), today announced unaudited preliminary revenue results for the fourth quarter ended December 31, 2018.

- Omeros' preliminary (unaudited) total and OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% revenues for the fourth quarter of 2018 are expected to be a record high at approximately \$22.0 million compared to \$4.6 million in 3Q 2018 and \$13.8 million in the prior year fourth quarter. The increase from the prior periods reflects strong demand for OMIDRIA from ambulatory surgery centers (ASCs) and hospitals following reinstatement of pass-through reimbursement for OMIDRIA on October 1, 2018.
- As of December 31, 2018, days of wholesaler inventory on hand were consistent with historical norms.
- Increased utilization within commercial insurance and Veterans Health Administration systems contributed to the increased revenues.
- Units sold by wholesalers to ASCs and to hospitals (sell-through) as well as the number of purchasing hospital accounts for the fourth quarter 2018 each also represent a record high.
- Annualized run rate of weekly net sales in December was approximately \$100 million.

Consistent with Omeros' strategy, growing revenues from OMIDRIA are increasingly funding the progress across the company's pipeline, including the advancement of its OMS721 Phase 3 program in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). As reflected in an update recently submitted to clinicaltrials.gov, Omeros plans to keep the ongoing HSCT-TMA registration trial open through the submission, filing and review of the Biologics License Application (BLA) and the Marketing Authorization Application (MAA) in the U.S. and Europe, respectively, to collect additional data. These data are expected to help provide healthcare professionals and payers with additional supporting information on the clinical use and value of OMS721 once approved. The update submitted by Omeros to clinicaltrials.gov has no effect on the overall timing, content or requirements of the OMS721 HSCT-TMA program, including the BLA and MAA, and the program remains on track.

"We are very pleased that demand for OMIDRIA, in its first quarter of restored separate payment, has not only returned quickly to the levels experienced prior to the expiration of pass-through reimbursement but that quarterly revenue and sell-through results are already setting new high-water marks," said Gregory A. Demopoulos, M.D., Omeros' chairman and chief executive officer. "We are also encouraged by the expanding coverage seen by commercial and Medicare Advantage payers and, with the addition of

OMIDRIA to its national formulary, by the VA. All of these data underscore the importance both of improved outcomes with OMIDRIA and of separate payment to ensuring patient access to the drug's benefits. As expected, revenues from sales of OMIDRIA ramped up throughout the fourth quarter, and we look forward to continued revenue growth in 2019 as we prepare to commercialize OMS721 for the treatment of stem cell transplant-associated TMA."

Omeros has released OMIDRIA fourth-quarter preliminary revenues for the purpose of providing transparency in the unique setting of reinstatement of pass-through status and does not currently intend in the future to make public preliminary sales revenues on a routine basis. The company expects to release complete fourth-quarter and full-year 2018 financial results and to host a conference call by March 1, 2019.

About Omeros Corporation

Omeros is 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. The company's drug product OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is marketed for use during cataract surgery or intraocular lens (IOL) replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. In the European Union, the European Commission has approved OMIDRIA for use in cataract surgery and other IOL replacement procedures to maintain mydriasis (pupil dilation), prevent miosis (pupil constriction), and to reduce postoperative eye pain. Omeros has multiple Phase 3 and Phase 2 clinical-stage development programs focused on: complement-associated thrombotic microangiopathies; complement-mediated glomerulonephropathies; cognitive impairment; and addictive and compulsive disorders. In addition, Omeros has a diverse group of preclinical programs and a proprietary G protein-coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and corresponding compounds, a number of which are in preclinical development. The company also exclusively possesses a novel antibody-generating platform.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are subject to the "safe harbor" created by those sections for such statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "likely", "look forward to," "may," "plan," "potential," "predict," "project," "prospects," "should," "slated," "will," "would" and similar expressions and variations thereof. Forward-looking statements are based on management's beliefs and assumptions and on information available to management only as of the date of this press release. Omeros' actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, risks associated with product commercialization and commercial operations, unproven preclinical and clinical development activities, regulatory oversight, the ability for OMIDRIA to obtain separate reimbursement as part of CMS' OPPS, intellectual property claims, competitive developments, litigation, and the risks, uncertainties and other factors described under the heading "Risk Factors" in the company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 8, 2018. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and the company assumes no obligation to update these forward-looking statements, even if new information becomes available in the future.

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