



NEWS RELEASE

Omeros Corporation Reports Third Quarter 2018 Financial Results

2018-11-08

– Conference Call Friday, November 9th at 8:30 a.m. ET –

SEATTLE--(BUSINESS WIRE)--Nov. 8, 2018-- Omeros Corporation (NASDAQ: OMER) today announced recent highlights and developments as well as financial results for the third quarter ended September 30, 2018, which include:

- 3Q 2018 total and OMIDRIA® revenues were \$4.6 million, compared to \$1.7 million in 2Q 2018 and \$21.7 million in last year's third quarter. The increase over the last quarter is primarily due to revenues from the company's wholesalers in anticipation of renewed buying from ambulatory surgery centers (ASCs) and hospitals as a result of the reinstatement of pass-through reimbursement on October 1, 2018. The decrease from 3Q 2017 is due to the significant reduction in OMIDRIA usage by ASCs and hospitals in 3Q 2018 as a result of the absence of transitional pass-through reimbursement, which expired for OMIDRIA on January 1, 2018.
- Sell-through for October 2018 was 81% of sell-through in October 2017, which was our highest month of OMIDRIA sell-through to date.
- The recently released 2019 Outpatient Prospective Payment System (OPPS) final rule for the Centers for Medicare & Medicaid Services (CMS) includes provisions that are expected to provide for continued separate reimbursement for OMIDRIA after its recently reinstated pass-through status expires on October 1, 2020.

- Net loss in 3Q 2018 was \$39.5 million, or \$0.81 per share. Non-cash expenses were \$5.0 million, or \$0.10 per share.
- At September 30, 2018, the company had cash, cash equivalents and short-term investments available for operations of \$55.2 million.
- Results from the second reported cohort from Omeros' ongoing Phase 2 clinical trial in patients with Immunoglobulin A (IgA) nephropathy are consistent with the first cohort and demonstrated significant reductions in proteinuria ranging from greater than 50% to approximately 70% following extended treatment with OMS721.
- Recent meetings with multiple European national regulatory authorities resulted in uniform recommendations to submit a marketing authorization application, or MAA, for full approval of OMS721 for hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). Based on these meetings, Omeros has filed with the European Medicines Agency (EMA) a letter of intent to submit a marketing authorization application (MAA) via EMA's centralized procedure for approval of OMS721 for the treatment of HSCT-TMA and expects to receive assignment of a rapporteur and co-rapporteur by year end.
- The U.S. Food and Drug Administration (FDA) granted orphan drug designation to OMS721 for the treatment of HSCT-TMA, and the European Commission adopted a decision designating OMS721 as an Orphan Medicinal Product in the European Union for treatment in HSCT.
- Omeros' Phase 1 clinical trial for the company's lead phosphodiesterase 7 (PDE7) inhibitor OMS527 is underway, and the company has completed dosing in the first six cohorts of subjects, which included a food effect study. The compound has been well tolerated, and pharmacokinetic data support once-daily dosing, with or without food.

"We are pleased with the strong demand that we are seeing for OMIDRIA so soon following reinstatement of its pass-through payment status," said Gregory A. Demopoulos, M.D., chairman and chief executive officer of Omeros. "We expect that ramp to continue, generating a growing revenue stream to support our advancing pipeline. Omeros' lead product in that pipeline, our MASP-2 inhibitor OMS721, is driving toward U.S. and European commercialization in stem-cell TMA, we believe that the recent positive data in IgA nephropathy meaningfully de-risks the program's Phase 3 pivotal trial, and the aHUS program is enrolling. Our Phase 1 trial for our PDE7 inhibitor OMS527 is progressing nicely and, to date, the drug is demonstrating a good safety profile and predictable pharmacokinetics. OMS906, our MASP-3 inhibitor, is targeted for clinical development in late 2019 followed by our orally administered MASP-2 inhibitors, which are slated to enter the clinic in 2020. Our team has done a great job managing the advancement of these assets while focusing on delivering our products to the market to meet the urgent needs of patients, and I expect that we will see equal or greater achievements in 2019."

Third Quarter and Recent Developments

- Developments regarding OMIDRIA (phenylephrine and ketorolac intraocular solution) 1% / 0.3% include:

- Pass-through status for OMIDRIA was reinitiated on October 1, 2018 following a three-quarter hiatus. Sell-through for October 2018 has already reached 81% of sell-through achieved in October 2017, which was our highest month of OMIDRIA sell-through to date.
- CMS recently released its 2019 final rule for the OPPS. In it, CMS indicated that it will separately pay in the ASC setting for non-opioid drugs used during surgery that have an FDA-approved indication for postoperative pain relief and that are packaged in calendar year 2019. Although OMIDRIA is not specifically named because it is paid separately until October 1, 2020, Omeros believes that OMIDRIA meets the definition for this non-opioid exclusion. The preamble to this section of the OPPS Final Rule indicates that CMS will apply the exclusion from packaged payment to other drugs in the future if they meet the criteria. The OPPS Final Rule also states that CMS will consider in future rulemaking a policy that pays separately for drugs used during cataract surgery that have an FDA-approved indication to address postoperative issues. Omeros believes that OMIDRIA also meets this definition.
- The most recent manuscripts published or submitted for publication reporting the results of “real-world” clinical studies show that, compared to epinephrine in both conventional and femtosecond-laser assisted cataract surgery, OMIDRIA decreased the need for pupil expansion devices and shortened surgical times for cataract surgery, demonstrating how the use of OMIDRIA may increase the efficiency and reduce the costs of cataract surgery. These studies add to the growing body of published real-world clinical studies demonstrating significant benefits of OMIDRIA to both patients and surgeons across routine and complex cataract surgery cases.
- Developments regarding OMS721, Omeros’ lead human monoclonal antibody in its mannan-binding lectin-associated serine protease-2 (MASP-2) programs for the treatment of HSCT-TMA, IgA nephropathy, and atypical hemolytic uremic syndrome (aHUS), include:
 - The company met recently with multiple European national regulatory authorities focused on approval pathways for OMS721 for the treatment of HSCT-TMA. Feedback from the European national regulatory authorities has been uniformly positive, each recommending that Omeros submit an MAA for full approval of OMS721 in HSCT-TMA.
 - The company has filed with the European Medicines Agency a letter of intent to submit an MAA for OMS721 in HSCT-TMA via the centralized procedure and looks forward to receiving assignment of a rapporteur and co-rapporteur who will work with the company through the MAA submission and review process. Close interactions with the FDA and European regulatory agencies are ongoing and the company continues preparations for U.S. Biologics License Application (BLA) and European MAA submissions.
 - The company is preparing to begin collection of chart-review-based historical data following finalization of the data collection and analysis plan. The comparison of OMS721-treated patients to the historical control is designed to support accelerated approval in the U.S. and full approval in Europe.

- In October 2018, Omeros reported positive results in patients with IgA nephropathy from the second reported cohort of the ongoing Phase 2 clinical trial. The cohort was designed to provide descriptive data on the effects of single and multiple 12-week courses of treatment with OMS721 in a small number of patients. Unlike the first cohort, patients in the second cohort were not taking steroids. Twelve patients were enrolled and data were reported for the nine evaluable patients. At the time of reporting, all patients had completed at least one 12-week course of treatment with either OMS721 or placebo and were eligible for OMS721 treatment during the dosing-extension phase of the study.
 - At week 18, median reduction in proteinuria was 18.4 percent in the five OMS721-treated patients and 18.0 percent in the four placebo patients.
 - Eight patients had at least 18 weeks of data and received at least one 12-week course of treatment with OMS721. In these patients, median reduction from baseline proteinuria was 56 percent; and five of the eight had received only one course of OMS721 treatment.
 - Four patients in this OMS721 dosing-extension period have reached between nine and 12 months beyond baseline, and show reductions in proteinuria of 54 percent, 57 percent, 65 percent, and 68 percent. At most recent assessment, two of these four patients continued to demonstrate sustained reductions in proteinuria for 2.5 and 5 months, respectively, after cessation of treatment with OMS721; the other two patients just recently completed treatment courses.
 - The company and international experts in IgA nephropathy believe that these data are strongly positive and supportive of a disease modifying effect, with the magnitude of proteinuria reduction consistent with that from the previously reported first cohort of the clinical trial.
- Omeros announced in October 2018 that the FDA granted orphan drug designation to OMS721 for the treatment of HSCT-TMA and announced in July 2018 that the European Commission adopted a decision designating OMS721 as an Orphan Medicinal Product in the European Union for treatment in HSCT.
- In Omeros' phosphodiesterase 7, or PDE7, program, the company is developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders. A Phase 1 single-ascending- and multiple-ascending-dose clinical trial is underway with the company's lead PDE7 inhibitor and is designed to assess safety and pharmacokinetics of the compound in healthy subjects. The company has completed dosing in the first six cohorts of subjects, including one cohort that assessed food effect. The compound to date has been well tolerated and pharmacokinetic data support once-daily dosing, with or without food. Completion of the Phase 1 trial is slated for the first half of 2019. Following Phase 1 completion, if successful, Omeros plans to conduct an initial OMS527 Phase 2 clinical trial in patients with nicotine addiction.

Financial Results

For the quarter ended September 30, 2018, revenues were \$4.6 million, all relating to sales of OMIDRIA. This compares to OMIDRIA revenues of \$1.7 million in 2Q 2018 and \$21.7 million for the third quarter of 2017. The

increase over the last quarter is primarily due to revenues from the company's wholesalers in anticipation of renewed buying from ASCs and hospitals as a result of the reinstatement of pass-through reimbursement on October 1, 2018. The decrease from 3Q 2017 is due to the significant reduction in OMIDRIA use by ASCs and hospitals in 3Q 2018 as a result of the absence of transitional pass-through reimbursement, which expired for OMIDRIA beginning January 1, 2018.

During the last week of September and for October 2018, the company saw OMIDRIA sales from the company's wholesalers to its customers (sell-through) increase significantly compared to the first three quarters of 2018. In addition, in October 2018, the company's ASC and hospital customers purchased approximately 17,500 units of OMIDRIA from its wholesalers. October 2017 was the single highest sell-through month for OMIDRIA and in October 2018, the first month of pass-through reinstatement for OMIDRIA, the drug achieved 81% of this record high.

Total costs and expenses for the three months ended September 30, 2018 were \$40.1 million compared to \$26.8 million for the same period in 2017. The increase from the prior quarter was primarily due to higher manufacturing scale-up costs including the acquisition of manufacturing materials for the OMS721 programs and to incremental costs associated with initiating the OMS721 IgA nephropathy Phase 3 clinical trial and the July 2018 initiation of the company's Phase 1 clinical trial in OMS527. These increases were partially offset by decreased OMIDRIA patent litigation costs.

For the three months ended September 30, 2018, Omeros reported a net loss of \$39.5 million, or \$0.81 per share, which included non-cash expenses of \$5.0 million (\$0.10 per share). In comparison, for the prior year's third quarter Omeros reported a net loss of \$7.5 million, or \$0.16 per share including non-cash expenses of \$4.2 million (\$0.09 per share).

As of September 30, 2018, the company had \$55.2 million of cash, cash equivalents and short-term investments available for operations and another \$5.8 million in restricted investments.

Conference Call Details

Omeros' management will host a conference call to discuss the financial results and to provide an update on business activities. The call will be held at 5:30 a.m. Pacific Time; 8:30 a.m. Eastern Time tomorrow, Friday, November 9, 2018. To access the live conference call via phone, please dial (844) 831-4029 from the United States and Canada or (920) 663-6278 internationally. The participant passcode is 7771247. Please dial in approximately 10 minutes prior to the start of the call. A telephone replay will be available for one week following the call and may be accessed by dialing (855) 859-2056 from the United States and Canada or (404) 537-3406 internationally. The replay passcode is 7771247.

To access the live or subsequently archived webcast of the conference call on the internet, go to the company's website at www.omeross.com and select "Events" under the Investors section of the website. To access the live webcast, please connect to the website at least 15 minutes prior to the call to allow for any software download that may be necessary.

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.

OMEROS CORPORATION
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenue:				
Product sales, net	\$4,608	\$21,658	\$7,852	\$51,067
Costs and expenses:				
Cost of product sales	36	184	355	613
Research and development	26,862	14,835	64,414	40,212
Selling, general and administrative	13,152	11,749	36,830	40,016
Total costs and expenses	40,050	26,768	101,599	80,841
Loss from operations	(35,442)	(5,110)	(93,747)	(29,774)
Interest expense	(4,602)	(2,780)	(11,104)	(8,166)
Other income	572	408	1,628	1,010
Net loss	\$(39,472)	\$(7,482)	\$(103,223)	\$(36,930)
Comprehensive loss	\$(39,472)	\$(7,482)	\$(103,223)	\$(36,930)
Basic and diluted net loss per share	\$(0.81)	\$(0.16)	\$(2.13)	\$(0.83)
Weighted-average shares used to compute basic and diluted net loss per share	48,647,416	46,262,211	48,437,870	44,709,418

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	September 30, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	\$ 55,156	\$ 83,749
Working capital	41,414	82,065
Restricted investments	5,779	5,835
Total assets	75,610	116,328
Total current liabilities	24,587	26,307
Notes payable and lease financing obligations, net	132,255	84,607
Accumulated deficit	(626,591)	(523,368)
Total shareholders' deficit	(88,997)	(2,814)

View source version on businesswire.com: <https://www.businesswire.com/news/home/20181108005963/en/>

Source: Omeros Corporation

Cook Williams Communications, Inc.
Jennifer Cook Williams, 360-668-3701
Investor and Media Relations
jennifer@cwcomm.org