NEWS RELEASE

Omeros Corporation Reports Fourth Quarter and Year-End 2018 Financial Results

2019-03-01

– Conference Call Today at 8:30 a.m. ET –

SEATTLE--(BUSINESS WIRE)--Mar. 1, 2019-- Omeros Corporation (NASDAQ: OMER), 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, disorders of the central nervous system and immune-related diseases, including cancers, today announced recent highlights and developments as well as financial results for the fourth quarter and year ended December 31, 2018, which include:

- 4Q 2018 total and OMIDRIA® revenues were $22.0 million, Omeros' highest revenue quarter to date. This compares 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.
- 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. The annualized run rate of weekly net sales in December was approximately $100 million.
- Full year 2018 OMIDRIA revenues were $29.9 million, a 53.9 percent decrease from the prior year. The decrease in OMIDRIA revenues in 2018 was primarily attributable to the lack of separate payment for

OMIDRIA under Medicare Part B from January 1, 2018 through September 30, 2018.

- Net loss in 4Q 2018 was $23.5 million, or $0.48 per share. Net loss for the full year 2018 was $126.8 million, or $2.61 per share. Non-cash expenses for 4Q and the full year of 2018 were $4.9 million, or $0.10 per share, and $18.7 million, or $0.39 per share, respectively.
- At December 31, 2018, the company had cash, cash equivalents and short-term investments available for operations of $60.5 million.
- Announced a streamlined plan for submission of a Biologics License Application for breakthrough therapy-designated narsoplimab in the treatment of HSCT-TMA following a meeting with FDA, which eliminated the need for a historical control, confirmed the appropriateness of a rolling submission and allows for not only accelerated approval but also full approval, with the determination to be made based on the submitted data.
- Reported positive data from patients in the second cohort of the Phase 2 IgA nephropathy trial. The data demonstrated that eGFR measurements remained stable, consistent with preservation of renal function and that reductions in proteinuria were consistent in magnitude to those in the first cohort of the Phase 2 trial, with improvements seen of greater than 50 to approximately 70 percent. A meeting with FDA resulted in revisions to the ongoing Phase 3 ARTEMIS-IGAN trial that are beneficial to the program.

“We’re pleased with the record OMIDRIA sales in the fourth quarter, which, together with stronger than historical demand for the product in January and February, form the basis for our expectations of substantial growth through 2019,” said Gregory A. Demopulos, M.D., Omeros’ chairman and chief executive officer. “Adding to our success with OMIDRIA, we have significantly advanced narsoplimab, our MASP-2 inhibitor, toward what we anticipate will be its first in a line of approvals, with our team currently preparing a BLA for stem cell-associated TMA. Behind stem-cell TMA, narsoplimab is in Phase 3 trials for IgA nephropathy and for aHUS, and we anticipate success here as well. OMS527 for addiction is in a Phase 1 clinical program, and our MASP-3 inhibitor, OMS906, and small-molecule inhibitor of MASP-2 are slated to enter the clinic next year. We’ve also expanded our pipeline into immuno-oncology with antagonists against GPR174, a novel target that, based on our animal and ex-vivo human data, increasingly appears to control a critical axis in the treatment of cancers. Across our programs, 2019 looks to be a year of tremendous achievements that we expect will ultimately improve – and save – patients’ lives.”

Fourth Quarter and Recent Developments

- Recent developments regarding OMIDRIA include the following:
    - Total revenues from OMIDRIA net sales reported in the fourth quarter were $22.0 million, Omeros’ highest quarterly revenue mark to date. This represents a 59 percent increase year-over-year compared to fourth quarter 2017, the last quarter before losing pass-through status on January 1, 2018.
    - In the fourth quarter of 2018, “sell through” – the number of units sold by wholesalers to ASCs and to hospitals during the quarter – was also the highest for any quarter of OMIDRIA sales to date. As a result, Omeros’ annualized run rate of weekly net sales in December 2018 was approximately $100 million.

- Recent developments regarding narsoplimab (formerly known as OMS721), Omeros' lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2) in Phase 3 clinical programs for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), Immunoglobulin A (IgA) nephropathy, and atypical hemolytic uremic syndrome (aHUS), include the following:
    - In January 2019, Omeros announced a finalized clinical plan for submission and approval of narsoplimab in IgA nephropathy. At a meeting with FDA to discuss Omeros' Phase 3 clinical program in this indication, it was confirmed that the Phase 3 trial's primary endpoint of assessment of proteinuria would be extended from 24 to 36 weeks, as requested by the company, to allow for additional narsoplimab dosing, if needed. These beneficial changes to the program continue to provide a path to accelerated, or even regular (full), approval based on those 36-week proteinuria data in either (i) the entire patient population (patients with baseline proteinuria greater than 1 gm/24 hours) or (ii) the high-risk subpopulation (those with baseline proteinuria of at least 2 gm/24 hours).
    - Also in January 2019, Omeros announced additional data from the total of eight IgA nephropathy patients in the second cohort of its Phase 2 trial who entered the extended follow-up period, all of whom received narsoplimab treatment during that period. Consistent with earlier positive results, the data showed at the most recent observation point for each patient: (i) estimated glomerular filtration rate (eGFR) measurements remaining stable, consistent with preservation of renal function; (ii) a 61 percent median reduction in proteinuria from baseline (across all eight patients, assessed at 31 weeks to 54 weeks post-baseline); (iii) five out of the eight patients achieving greater than 50 percent proteinuria reductions (median reduction of 65 percent), with two of those five having received their last narsoplimab administration five months earlier; and (iv) across the first (four patients) and second cohorts, a total of nine of 12 patients achieving greater than 50 percent reductions in proteinuria (median reduction of 65 percent).
    - In February 2019, Omeros announced a streamlined plan for submission of a Biologics License Application (BLA) for narsoplimab in the treatment of HSCT-TMA. Omeros recently met with FDA and agreed that a response-based analysis is the most appropriate and expeditious assessment for inclusion in a BLA for this indication, eliminating the need for a historical control. Data from patients already in the company's ongoing Phase 2 single-arm narsoplimab trial in HSCT-TMA will form the clinical basis for submission of the BLA. Survival assessments will now be secondary endpoints. FDA also confirmed that a rolling BLA submission is appropriate in this indication. This confirmation enables Omeros to submit first the non-clinical sections of the BLA, which, as planned, were written in late 2018. FDA further indicated that it will consider not only accelerated approval but also regular (full) approval for narsoplimab in stem-cell TMA, with the determination to be made based on the submitted data.
    - In October 2018, the FDA granted narsoplimab orphan drug designation in the treatment of HSCT-TMA.

Financial Results

Fourth Quarter 2018

For the quarter ended December 31, 2018, revenues were $22.0 million, all relating to sales of OMIDRIA. This compares to OMIDRIA revenues of $13.8 million for the same period in 2017. On a sequential quarter-over-quarter basis, OMIDRIA revenue increased by $17.4 million from the third quarter of 2018. The increase from the prior periods reflects strong demand for OMIDRIA from ASCs and hospitals following reinstatement of pass-through reimbursement on October 1, 2018.

Total operating costs and expenses for the three months ended December 31, 2018 were $40.5 million compared to $27.9 million for the same period in 2017. The change in the current year quarter was primarily due to increased research and development spending, which includes manufacturing scale-up costs, as we continue to advance narsoplimab for the treatment of HSCT-TMA towards regulatory submission in the U.S. and Europe, incremental Phase 3 clinical costs for our narsoplimab program in IgA nephropathy and increased Phase 1 clinical costs for OMS527, our PDE7 program for addiction and compulsive disorders.

For the three months ended December 31, 2018, Omeros reported a net loss of $23.5 million, or $0.48 per share, which included non-cash expenses of $4.9 million ($0.10 per share). This compares to the prior year's fourth quarter when Omeros reported a net loss of $16.6 million, or $0.34 per share, which included non-cash expenses of $4.5 million ($0.09 per share).

At December 31, 2018, the company had cash, cash equivalents and short-term investments available for operations of $60.5 million.

In November 2018Omeros issued $210.0 million of 6.25 percent unsecured Convertible Senior Notes due November 15, 2023. Concurrently, Omeros entered into a capped call transaction significantly reducing the potential dilution if the convertible notes are settled in common shares, and repaid all amounts then outstanding under its existing notes payable. Omeros recorded a one-time $13.0 million charge on early extinguishment of debt and a $13.0 million income tax benefit in the quarter ended December 31, 2018.

Full Year 2018

Revenues for the full year 2018 were $29.9 million, a decrease of 53.9 percent compared to $64.8 million for the full year 2017. The decrease in OMIDRIA revenue in 2018 was primarily attributable to the lack of separate payment for OMIDRIA under Medicare Part B from January 1, 2018 through September 30, 2018.

Total operating costs and expenses for the year ended December 31, 2018 were $142.1 million, an increase of

$33.4 million compared to 2017. The increase from the prior year related primarily to higher third-party manufacturing scale-up costs for our narsoplimab program as we continue to increase our production capacity to meet anticipated clinical and commercial requirements, as well as higher costs associated with initiation of our Phase 3 clinical trial of narsoplimab in IgA nephropathy and our Phase 1 clinical trial for OMS527, our PDE7 program for addiction and compulsive disorders.

For the full year 2018, Omeros reported a net loss of $126.8 million, or $2.61 per share, including non-cash expenses of $18.7 million, or $0.39 per share. This compares to a net loss of $53.5 million, or $1.17 per share in 2017, including non-cash expenses of $17.4 million, or $0.38 per share.

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 today at 5:30 a.m. Pacific Time; 8:30 a.m. Eastern Time. 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 3544038. 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 3544038.

To access the live or subsequently archived webcast of the conference call on the internet, go to the company's website at **www.omeros.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, disorders of the central nervous system and immune-related diseases, including cancers. 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, 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,” “should,” “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, intellectual property claims, competitive developments, litigation, and the risks, uncertainties and other factors described under the heading “Risk Factors” in the company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2019. 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 December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	$22,017	$13,760	$29,868	$64,826
Costs and expenses:				
Cost of product sales	157	466	512	1,078
Research and development	25,446	15,387	89,860	55,599
Selling, general and administrative	14,888	12,028	51,718	52,044
Total costs and expenses	40,491	27,881	142,090	108,721

Loss from operations	(18,474)	(14,121)	(112,222)	(43,895)
Loss on early extinguishment of debt	(12,993)	—	(12,993)	—
Interest expense	(5,149)	(2,864)	(16,252)	(11,030)
Other income	153	434	1,781	1,444
Loss before income taxes	(36,463)	(16,551)	(139,686)	(53,481)
Income tax benefit	12,929	—	12,929	—
Net loss	$(23,534)	$(16,551)	$(126,757)	$(53,481)
Basic and diluted net loss per share	$(0.48)	$(0.34)	$(2.61)	$(1.17)
Weighted-average shares used to compute basic and diluted net loss per share	49,010,677	48,029,195	48,582,636	45,539,362

OMEROS CORPORATION

UNAUDITED CONSOLIDATED BALANCE SHEET DATA

(In thousands)

	December 31, 2018	December 31, 2017
Cash, cash equivalents and short-term investments	$ 60,498	$ 83,749
Working capital	52,511	82,065
Restricted investments	1,154	5,835
Total assets	95,936	116,328
Total current liabilities	37,356	26,307
Notes payable and lease financing obligations, net	2,467	84,117
Unsecured convertible senior notes, net	148,981	—
Accumulated deficit	650,125	523,368
Total shareholders' deficit	100,156	2,814

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Source: Omeros Corporation

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