NEWS RELEASE

Omeros Corporation Reports First Quarter 2019 Financial Results

2019-05-09

– Conference Call Today at 4:30 p.m. ET –

SEATTLE--(BUSINESS WIRE)--May 9, 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 first quarter ended March 31, 2019, which include:

- 1Q 2019 total and OMIDRIA® revenues were $21.8 million compared to $1.6 million and $22.0 million in the first and fourth quarters of 2018, respectively. 1Q 2019 revenues reflect the seasonally lower volume of cataract surgery performed in the first quarter and the timing of normal wholesaler purchases shifting from the end of March to the first week of April.
- “Sell-through” – the number of units sold by wholesalers to ASCs and to hospitals – for 1Q 2019 was a record high, increasing 14 percent from the previous high-water mark set in 4Q 2018. Sell-through in the current quarter has continued to grow at a double-digit rate over the same period in the first quarter.
- Net loss in 1Q 2019 was $24.3 million, or $0.50 per share, which includes non-cash expenses of $6.0 million, or $0.12 per share. Overall decrease in cash, cash equivalents and short-term investments for the quarter was

$13.3 million.

- At March 31, 2019, the company had cash, cash equivalents and short-term investments available for operations of $47.2 million.
- Since the previously reported FDA meeting held in the first quarter of 2019, which resulted in a streamlined path to submission of a Biologics License Application (BLA) for narsoplimab in HSCT-TMA, the company has had two additional meetings with FDA. The first covered chemistry, manufacturing and controls (CMC), and the company's CMC commercialization plan remains on track. In the second, a clinical meeting, Omeros reached agreement with FDA on the large majority of the criteria for the primary endpoint. The company expects to complete agreement on the few remaining details in the very near future and is confident that the efficacy and safety data for narsoplimab will support BLA approval in HSCT-TMA.
- CMS recently issued a preliminary decision to establish a unique permanent HCPCS J-code for OMIDRIA. The decision is expected to be finalized no later than November with the J-code becoming effective on the first day of the following quarter. A J-code provides a uniform, simpler and widely accepted process for providers to bill for OMIDRIA across both Medicare and commercial insurance plans.

"We are pleased with the company's performance to date in 2019, having made substantial strides on all fronts," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "Once again we saw OMIDRIA posting record quarterly sell-through numbers, up 14 percent over the record set in 4Q 2018, and the product's growth trajectory has continued this quarter. Narsoplimab is advancing across three Phase 3 programs and, based on recent interactions with FDA, we expect very soon to wrap up the remaining criteria for the primary endpoint in stem cell TMA, are confident that our data will support a BLA approval and are moving forward with preparations for a commercial launch. Our PDE7 inhibitor, OMS527, is also faring well in its Phase 1 clinical trial, which is slated to finish later this quarter or next. Further expanding our complement franchise, both OMS906, our antibody against MASP-3, and our small-molecule MASP-2 inhibitor are planned to enter the clinic next year. We are also continuing to drive the development of our small-molecule compounds targeting GPR174, a receptor that increasingly appears to control a major cancer pathway. Across all of these efforts, our primary focus remains the patient. In over 600,000 procedures, cataract surgery patients have experienced the benefits of OMIDRIA, and we look forward to making narsoplimab commercially available worldwide in the near future."

First Quarter and Recent Developments

- Recent developments regarding OMIDRIA include the following:
    - The Centers for Medicare & Medicaid Services (CMS) issued a preliminary decision to establish a unique permanent Healthcare Common Procedure Coding System (HCPCS) J-code for OMIDRIA. The preliminary decision is included in the publicly available agenda for the agency's upcoming HCPCS Workgroup meeting on May 15, 2019. The decision is expected to be finalized no later than November 2019, with the code becoming effective on the first day of the following quarter. If finalized, assignment of a J-code

for OMIDRIA would provide a uniform and widely accepted process that is expected to simplify billing for the drug across Medicare as well as commercial insurance plans.

- In May 2019, the results of a "real-world" clinical study were presented at the annual meeting of the American Society of Cataract and Refractive Surgery and American Society of Ophthalmic Administrators held in San Diego. The study compared the incidence of cystoid macular edema (CME), a sight-threatening complication of cataract surgery, in patients undergoing cataract surgery using OMIDRIA with postoperative NSAIDs alone versus those using postoperative corticosteroids, with and without NSAIDs, in the absence of OMIDRIA. The retrospective analysis of cataract surgery performed on 504 eyes (357 patients) showed that use of OMIDRIA reduced the incidence of CME by 3- to 12-fold compared to published data on cataract procedures performed without OMIDRIA. This study, together with the 17 peer-reviewed articles already published on the benefits of OMIDRIA, supports Omeros' ongoing efforts to secure permanent separate payment for the drug.

- Recent developments regarding narsoplimab, 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:
  - Omeros has had two additional meetings with the U.S. Food and Drug Administration (FDA) – one to cover chemistry, manufacturing and controls-related topics in preparation for commercialization and, most recently, to finalize the criteria for the HSCT-TMA trial's primary endpoint on which the clinical data will be assessed. The company's CMC commercialization plan remains on track. In the clinical meeting, Omeros reached agreement with FDA on the large majority of the criteria for the primary endpoint, which will include both laboratory and organ function components. The meeting included a detailed discussion of the primary endpoint and the company believes that it has a good understanding – and is comfortable with – FDA's position on the final few remaining details. Omeros expects to complete agreement on these last few details in the very near future. In light of discussions with FDA and the available data on narsoplimab treatment of HSCT-TMA patients, the company is confident that its efficacy and safety data will support approval.
  - In March 2019, Omeros launched a disease education initiative at the annual meeting of the European Society for Blood and Marrow Transplantation (EBMT) with a well-attended educational session sponsored by Omeros and entitled "How do I…diagnose HSCT-TMA." A focus of the session was the relationship between HSCT-TMA and the broader syndrome of disorders caused by endothelial injury, which is important across the company's development of MASP-2 inhibitors, including narsoplimab.
  - Omeros also announced the presentation at EBMT of a case report of resolution of gastrointestinal HSCT-TMA following narsoplimab treatment. The case was presented by Rafael Duarte M.D., Ph.D., F.R.C.P., Associate Professor, Head of Hematopoietic Transplantation and Hemato-oncology Section,

University Hospital Puerta de Hierro Majadahonda, Madrid and Secretary of the EBMT. Dr. Duarte described an 18-year-old patient with biopsy-proven HSCT-TMA of the gastrointestinal tract causing severe gastrointestinal bleeding requiring transfusions. Upon receiving narsoplimab, her TMA resolved and all transfusions were discontinued. The patient continues to do well after cessation of narsoplimab treatment.

- Omeros' Phase 3 trial evaluating narsoplimab for IgA nephropathy, referred to as ARTEMIS-IGAN, continues to enroll. Results from the Phase 2 study of narsoplimab in IgA nephropathy are expected to be presented at the annual Congress of the European Renal Association - European Dialysis and Transplant Association in Budapest in June. In addition, together with its Academic Leadership Committee of international experts on IgA nephropathy, the company is preparing a series of manuscripts directed to narsoplimab and its IgA nephropathy program with the first manuscript planned for submission soon.

- Updates regarding Omeros' other development programs and platforms include the following:
  - The development of small-molecule MASP-2 inhibitors continues, and lead compounds are being optimized for potency, oral bioavailability and target selectivity. Omeros expects to enter the clinic with an orally administered MASP-2 inhibitor next year.
  - The company's MASP-3 inhibitor, OMS906, is expected to enter clinical trials in the first half of 2020.
  - In the company's Phase 1 trial for OMS527, which targets treatment of addiction and compulsive disorders, the company has completed dosing all six cohorts in the single-ascending-dose portion of the trial, and three multiple-ascending-dose cohorts. The trial is expected to be completed during the second or third quarter of this year. The drug has been well tolerated and pharmacokinetic data are consistent with once-daily dosing with or without food. A Phase 2a study targeting nicotine addiction is planned assuming successful completion of Phase 1.
  - In Omeros' proprietary G protein coupled receptor (GPCR) platform, development efforts are focused on several targets, including GPR174. Based on its data, the company believes that GPR174 controls a major pathway in cancer, and modulation of the receptor could provide a seminal advance in immuno-oncologic treatments for a wide range of solid and liquid tumors. Development continues on small molecule compounds targeting GPR174 with the objective of entering the clinic as soon as possible.

- In May 2019, Omeros launched a new corporate website at **www.omeros.com**.
- Omeros has approval for and is finalizing an accounts receivable-based line of credit that, if the company chooses to implement it, would provide for borrowing availability of up to $50 million depending on the company's available borrowing base.

Financial Results

For the quarter ended March 31, 2018, revenues were $21.8 million, all relating to sales of OMIDRIA. This compares

to OMIDRIA revenues of $1.6 million and of $22.0 million in the first and fourth quarters of 2018, respectively. 1Q 2019 revenues reflect the seasonally lower volume of cataract surgery performed in the first quarter and the timing of normal wholesaler purchases shifting from the end of March to the first two days of April, when net sales to wholesalers were approximately $2.4 million. Inventory units on hand at wholesalers at December 31, 2018 and March 31, 2019 were effectively the same. Gross-to-net deductions decreased from 28.3 percent in 4Q 2018 to 27.0 percent in 1Q 2019.

Sell-through for 1Q 2019 was a record high, increasing 14 percent from the previous high-water mark set in the 4Q 2018. Sell-through in the current quarter has continued to grow at a double-digit rate over the same period in the first quarter.

Total costs and expenses for the three months ended March 31, 2019 were $41.0 million compared to $29.3 million for the same period in 2018. The increase in the current year quarter was due 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 increased expenses associated with pre-commercialization activities for narsoplimab and sales and marketing costs related to the re-introduction of OMIDRIA.

For the three months ended March 31, 2019, Omeros reported a net loss of $24.3 million, or $0.50 per share, which included non-cash expenses of $6.0 million, or $0.12 per share. This compares to the prior year's first quarter for which Omeros reported a net loss of $30.1 million, or $0.62 per share, which included non-cash expenses of $4.3 million, or $0.09 per share.

Overall decrease in cash, cash equivalents and short-term investments for 1Q 2019 was $13.3 million. As of March 31, 2018, the company had $47.2 million of cash, cash equivalents and short-term investments available for operations.

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 1:30 p.m. Pacific Time; 4:30 p.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 4095776. 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 4095776.

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,” “objective,” “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, as supplemented from time to time by the company's Quarterly Reports on Form 10-Q. 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 March 31,	
	2019	2018
Revenue:		
Product sales, net	$ 21,779	$ 1,588
Costs and expenses:		
Cost of product sales	131	203
Research and development	26,255	18,140
Selling, general and administrative	14,632	10,934
Total costs and expenses	41,018	29,277
Loss from operations	(19,239)	(27,689)
Interest expense	(5,600)	(2,825)
Other income	494	460
Net loss	$ (24,345)	$ (30,054)
Comprehensive loss	$ (24,345)	$ (30,054)
Basic and diluted net loss per share	$ (0.50)	$ (0.62)
Weighted-average shares used to compute basic and diluted net loss per share	49,014,009	48,284,019

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	March 31, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 47,222	$ 60,498
Working capital	33,780	52,511
Restricted investments	1,154	1,154
Total assets	101,246	95,936
Total current liabilities	44,505	37,356
Lease liabilities	29,139	2,467
Convertible Senior Notes	151,182	148,981
Accumulated deficit	(674,470)	(650,125)
Total shareholders' deficit	(121,019)	(100,156)

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Source: Omeros Corporation

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