Omeros Corporation Reports Third Quarter 2019 Financial Results

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

SEATTLE, WA – November 12, 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 third quarter ended September 30, 2019.

Third Quarter 2019 Financial Highlights

- 3Q 2019 revenues were $29.9 million, another quarter of record sales of OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%. This compares to $26.8 million in 2Q 2019, an increase of $3.1 million, or 12 percent.
- Net loss in 3Q 2019 was $16.5 million, or $0.33 per share. This compares to a net loss $14.5 million, or $0.29 per share, in 2Q 2019. Net loss in each period included non-cash expenses of $6.3 million, or $0.13 per share.
- At September 30, 2019, Omeros had cash, cash equivalents and short-term investments available for operations of $27.3 million, a decrease of $4.5 million from June 30, 2019. Accounts receivable at September 30, 2019 were $29.9 million.
- Omeros has a $50-million revolving line of credit facility with Silicon Valley Bank. The line of credit provides for borrowing availability of up to the lesser of $50 million and 85 percent of eligible accounts receivable, subject to applicable reserves. As of September 30, 2019 there were no borrowings outstanding.

Recent Business Highlights

- Submitted to the U.S. Food and Drug Administration (FDA) the nonclinical sections of the Biologics License Application (BLA) for narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA).
- Received from the Pediatric Committee of the European Medicines Agency (EMA) a positive opinion on the pediatric investigation plan for narsoplimab in the treatment of HSCT-TMA.
- Reported positive results from a Phase 1 study of the lead compound in Omeros' OMS527 program focused on development of phosphodiesterase 7 (PDE7) inhibitors for the treatment of addiction and compulsive disorders. In the double blind, randomized Phase 1 study, the study drug, referred to as OMS182399, met the primary endpoints of safety and tolerability and showed a favorable pharmacokinetic profile supporting once-daily dosing.
- Presented data on a series of discoveries showing that GPR174, a member of the family of G protein-coupled receptors (GPCRs), controls a new axis in cancer immunity. In addition to demonstrating the potential of GPR174 as a standalone anti-cancer agent, these data show that the combined inhibition of both GPR174 and the adenosine pathway synergistically enhances T-cell response. This synergistically enhanced T-cell response could significantly improve the effectiveness of checkpoint inhibitors and other anti-cancer drugs.
- Scientists from Omeros along with academic collaborators from the University of Toronto were awarded the Prix Galien Canada Research Award for 2019 in recognition of their development of the drug discovery technologies underlying Omeros' GPCR platform. The Prix Galien is the most prestigious award in the field of Canadian pharmaceutical research and innovation and recognizes the research team judged to have made the most significant contribution.

“Initiating submission of our rolling BLA for narsoplimab in stem cell transplant-associated TMA is a significant milestone on our path to becoming a multi-product commercial biopharmaceutical company and, more importantly, is a major advance in our mission to treat these patients,” said Gregory A. Demopulos, M.D., Omeros’ chairman and chief executive officer. “We are on track to complete submission of our BLA in the first half of 2020 and preparations for the anticipated commercial launch of narsoplimab are also progressing. We continue to grow utilization of OMIDRIA, delivering record quarterly sales in Q3 and projecting a new all-time high in the fourth quarter. The remainder of our pipeline assets are also progressing – OMS527 has successfully completed its Phase 1 trial in our addiction program, our MASP-3 inhibitor OMS906 is on track to enter the clinic in the first half of next year, and our GPR174 immuno-oncology program continues to generate exciting new *in vivo* data, which will be presented for the first time later this month at the AACR conference in Boston.”

Other Business Updates and Developments

Recent developments regarding OMIDRIA include the following:

- The new product-specific permanent J-code for OMIDRIA became effective October 1, 2019. J-codes standardize the submission and payment of insurance claims across Medicare, Medicare Advantage, Medicaid and commercial insurance plans. The J-code has been broadly uploaded to Medicare and commercial payer systems nationwide and is expected to expand reimbursement to commercial, Medicare Advantage and Medicaid insurers that would not reimburse for OMIDRIA under the prior C-code and to enable access to the increasing number of cataract procedures performed in the physician office setting.
- In October, a manuscript authored by Keith Walter, M.D. of Wake Forest University, was accepted for publication in the peer-reviewed *Journal of Cataract and Refractive Surgery*. Dr. Walter’s study consisted of a retrospective analysis of 504 eyes (357 patients) on whom he had performed cataract surgery using OMIDRIA plus only a topical non-steroidal anti-inflammatory drug (NSAID), assessing the incidence of CME. The control group consisted of a collection of single and meta-analytic studies published in the peer-reviewed literature in which steroids, with and without topical NSAIDs, were used in cataract surgery in the absence of OMIDRIA. Of the 504 eyes treated with OMIDRIA, only two developed postoperative CME, an incidence of 0.39 percent, which is 3- to 12-fold lower than the CME rates in the published peer-reviewed studies.
- On November 1, 2019, the Centers for Medicare and Medicaid Services (CMS) issued the 2020 final rule for its outpatient prospective payment system (OPPS). CMS had described criteria that must be met in order for products to be eligible for separate payment under legislation requiring CMS to review its OPPS payments with a goal of ensuring that there are not financial incentives to use opioids for pain management instead of non-opioid alternatives. Although Omeros submitted to CMS data for OMIDRIA that meet the criteria, CMS declined in its 2020 final rule to grant separate payment for OMIDRIA beyond the expiration of its current pass through status on September 30, 2020. CMS indicated it would continue to analyze evidence and monitor utilization of OMIDRIA and Omeros intends to continue its administrative and legislative efforts to secure ongoing separate payment for OMIDRIA.
- On November 4, 2019 the results of an independent investigator study of the effect of OMIDRIA use on the utilization of fentanyl, an opioid, in cataract surgery were published in the peer-reviewed journal *Clinical Ophthalmology*. The article, *The Effect of Phenylephrine/Ketorolac Intracameral Solution 1%/0.3% on Pain and Opioid Use During Cataract Surgery*, is authored by the study investigator Eric D. Donnenfeld, M.D., Clinical Professor of Ophthalmology at New York University and recent past president of the American Society of Cataract and Refractive Surgery. The prospective, controlled study showed that use of OMIDRIA in cataract surgery had a direct, clinically meaningful and statistically significant effect on reduction in fentanyl use (77% reduction, $p = 0.006$) while reducing visual analog scale (VAS) pain scores by approximately 50 percent ($p < 0.0001$).

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 HSCT-TMA, Immunoglobulin A (IgA) nephropathy, and atypical hemolytic uremic syndrome (aHUS), include the following:

- In October, Omeros submitted to FDA the nonclinical (i.e., pharmacology, pharmacokinetics and toxicology) data, study reports, overview and summary sections of its rolling BLA for narsoplimab to treat HSCT-TMA. Once all clinical data collection, dataset compilation and data analyses are complete, the clinical sections of the BLA

will be submitted, followed by the quality (i.e., chemistry, manufacturing and controls) sections. Submission of the clinical and quality sections remains on track for scheduled completion in the first half of next year.

- The Pediatric Committee of the EMA issued a positive opinion for Omeros' pediatric investigation plan (PIP) for narsoplimab in the treatment of HSCT-TMA. Agreement with the pediatric committee on a PIP outlining a development program for the investigational product in the pediatric population is a prerequisite to EMA's acceptance of a Marketing Authorization Application (MAA) for the product. Omeros received a deferral for completion of its pediatric plan until after EMA approval of the MAA planned for submission to EMA for narsoplimab in the treatment of HSCT-TMA. With successful completion of the PIP, narsoplimab would be eligible for up to an additional two years of marketing exclusivity.
- Omeros' Phase 3 trial evaluating narsoplimab for IgA nephropathy, referred to as ARTEMIS-IGAN, continues enrollment at an increasing number of sites in the U.S. and internationally.
- A manuscript prepared by Omeros' Academic Leadership Committee detailing the clinical data from the Phase 2 IgA nephropathy program is expected to be published in a peer-reviewed journal. In addition, a report detailing the response to narsoplimab treatment by a patient with IgA vasculitis-associated nephritis and rapidly progressive glomerulonephritis has been submitted for publication.

Updates regarding Omeros' other development programs and platforms include the following:

- IND-enabling toxicology studies have begun for OMS906, Omeros' MASP-3 inhibitor, in advance of clinical entry slated for the first half of next year. Targeting subcutaneous dosing of twice-monthly or less frequently, this program is initially targeting paroxysmal nocturnal hemoglobinuria.

- Omeros continues life-cycle management within its MASP-2 program. These efforts are directed to development of a longer-acting second-generation antibody against MASP-2 as well as an orally available small-molecule inhibitor of MASP-2, both targeted for clinical entry in 2021.

- A presentation entitled "Phosphatidylserine suppresses T cells through GPR174, and co-inhibition of adenosine receptors and GPR174 synergistically enhances T cell responses" will be made at the American Association for Cancer Research conference on Tumor Immunology and Immunotherapy to be held in Boston, November 17-20, 2019. It will include additional animal data that validate GPR174 inhibition for cancer immunotherapy. The company's GPR174 program has also been selected for participation in the 2019 Immuno-Oncology Congress of the European Society for Medical Oncology to be held in Geneva, December 11-14, 2019.

Financial Results

3Q 2019 revenues, all related to sales of OMIDRIA, were $29.9 million, a new record high. On a sequential quarter-over-quarter basis, OMIDRIA revenues increased by $3.1 million, or 12 percent, from the $26.8 million achieved in 2Q 2019. The increase is due to a growing number of purchasing accounts as well as deeper penetration within accounts across hospitals, ASCs, Veterans Administration and other government payers.

Gross-to-net deductions in 3Q 2019 remained consistent with those in 2Q 2019 at 28 percent

3Q 2019 costs and expenses were $41.0 million compared to $36.1 million for Q2 2019. The increase reflected incremental narsoplimab manufacturing costs associated with the commencement of full-scale drug substance manufacturing in 3Q 2019 together with increased manufacturing scale-up costs in our OMS906 program in advance of planned clinical entry next year. Selling, general and administrative expenses were $16.9 million for both 2Q and 3Q 2019.

For 3Q 2019, Omeros reported a net loss of $16.5 million, or $0.33 per share, compared to a net loss of $14.5 million, or $0.29 per share, in 2Q 2019. Net loss in both 2Q 2019 and 3Q 2019 included non-cash expenses of $6.3 million ($0.13 per share).

As of September 30, 2019, Omeros had $27.3 million of cash, cash equivalents and short-term investments available for operations, a decrease of $4.5 million from June 30, 2019. Accounts receivable at September 30, 2019 were $29.9 million.

Omeros has a $50-million revolving line of credit facility with Silicon Valley Bank. The line of credit provides for borrowing availability of up to the lesser of $50 million and 85 percent of eligible accounts receivable, subject to applicable reserves. As of September 30, 2019, there were no borrowings outstanding.

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 9699377. 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 9699377.

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 an innovative biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting complement-mediated diseases, disorders of the central nervous system and immune-related diseases, including cancers. In addition to its commercial drug OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%, Omeros has multiple Phase 3 and Phase 2 clinical-stage development programs focused on complement-mediated disorders and substance abuse, as well as a diverse group of preclinical programs including GPR174, a novel target in immuno-oncology that modulates a new cancer immunity axis recently discovered by Omeros. Small-molecule inhibitors of GPR174 are part of Omeros' proprietary G protein-coupled receptor (GPCR) platform through which it controls 54 new GPCR drug targets and their corresponding compounds. 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," "slate," "target," "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, changes in reimbursement and payment policies by government and commercial payers or the application of such policies, 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.

Contact:

Jennifer Cook Williams
Cook Williams Communications, Inc.
Investor and Media Relations
360.668.3701
jennifer@cwcomm.org

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product sales, net	$ 29,856	$ 4,608	$ 78,389	$ 7,852
Costs and expenses:				
Cost of product sales	278	36	464	355
Research and development	23,746	26,862	69,108	64,414
Selling, general and administrative	16,933	13,152	48,493	36,830
Total costs and expenses	40,957	40,050	118,065	101,599
Loss from operations	(11,101)	(35,442)	(39,676)	(93,747)
Interest expense	(5,715)	(4,602)	(16,846)	(11,104)
Other income	353	572	1,261	1,628
Net loss	$ (16,463)	$ (39,472)	$ (55,261)	$ (103,223)
Comprehensive loss	$ (16,463)	$ (39,472)	$ (55,261)	$ (103,223)
Basic and diluted net loss per share	$ (0.33)	$ (0.81)	$ (1.12)	$ (2.13)
Weighted-average shares used to compute basic and diluted net loss per share	49,373,156	48,647,416	49,157,055	48,437,870

OMEROS CORPORATION
UNAUDITED CONSOLIDATED BALANCE SHEET DATA
(In thousands)

	September 30, 2019	December 31, 2018
Cash, cash equivalents and short-term investments	$ 27,342	$ 60,498
Working capital	17,046	52,511
Restricted investments	1,154	1,154
Total assets	91,263	95,936
Total current liabilities	46,753	37,356
Lease liabilities	31,709	2,467
Convertible Senior Notes	155,771	148,981
Accumulated deficit	(705,386)	(650,125)
Total shareholders' deficit	(139,915)	(100,156)