NEWS RELEASE

Omeros Corporation Reports Third Quarter 2023 Financial Results

2023-11-09

– Conference Call Today at 1:30 p.m. ET

SEATTLE--(BUSINESS WIRE)--Nov. 9, 2023-- Omeros Corporation (Nasdaq: OMER), a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders including complement-mediated diseases, cancers, and addictive and compulsive disorders, today announced recent highlights and developments as well as financial results for the third quarter ended September 30, 2023, which include:

- Net loss was $37.8 million for the quarter ended September 30, 2023, or $0.60 per share, compared to a net loss in the prior year quarter of $17.5 million, or $0.28 per share. The difference in the current year quarter net loss was primarily attributable to an incremental $18.9 million gain in discontinued operations in the prior year quarter due to the remeasurement of the OMIDRIA contract royalty asset. Net loss from continuing operations for the current quarter was $51.7 million compared to a net loss of $54.8 million in the prior year quarter. Cash burn for the quarter was $31.0 million.
- For the nine months ended September 30, 2023, our net loss was $108.8 million, or $1.73 per share, compared to a net loss of $81.3 million, or $1.30 per share, in the prior year period. The primary difference between the periods was the incremental gain from the remeasurement of the contract royalty asset in the prior year. Net loss from continuing operations for the nine months ended September 30, 2023 was $135.6

million compared to a net loss of $136.0 million in the prior year.

- For the third quarter of 2023, we earned OMIDRIA royalties of $10.0 million on Rayner Surgical Inc.'s U.S. net sales of $33.3 million. This compared to earned OMIDRIA royalties of $16.5 million during the third quarter of the prior year on U.S. net sales of $33.0 million. The difference in earned royalties reflects the decrease from 50 percent to 30 percent in the base royalty rate applicable to U.S. net sales of OMIDRIA, which occurred in December 2022 upon achievement of the $200.0 million milestone payment event.
- At September 30, 2023, we had $310.3 million of cash, cash equivalents and short-term investments available for operations and debt servicing. We expect to pay from our existing cash and investments on hand the $95 million principal balance due at maturity of our unsecured convertible senior notes on November 15, 2023.
- As part of our planned resubmission of our Biologics License Application ("BLA") for narsoplimab in hematopoietic stem cell transplant-associated thrombotic microangiopathy ("TA-TMA"), we have submitted to FDA a formal statistical analysis plan to compare survival data from an already-identified external source. We continue to target an FDA approval decision on our resubmitted BLA in mid-2024.
- We have discontinued our Phase 3 ARTEMIS-IGAN clinical trial evaluating narsoplimab for the treatment of immunoglobulin A ("IgA") nephropathy based on the results of a pre-specified interim analysis, as announced in October 2023. Topline results showed that narsoplimab did not reach statistically significant improvement over placebo on the primary efficacy endpoint of reduction in proteinuria. In-depth analysis of the ARTEMIS-IGAN data are ongoing.
- An abstract with new and updated data from our Phase 2 clinical trial evaluating OMS906 in patients with paroxysmal nocturnal hemoglobinuria ("PNH") who have not previously been treated with a complement inhibitor has been selected for podium presentation at the annual meeting of the American Society of Hematology ("ASH"), upcoming in December. The presentation describes the clinically meaningful and statistically significant effects of OMS906 across all measured markers of hemolysis, including hemoglobin, lactate dehydrogenase ("LDH"), and red blood cell clone size in PNH patients.
- The Phase 2 "switch-over" trial evaluating OMS906 in PNH patients who have demonstrated an unsatisfactory response to treatment with the C5 inhibitor ravulizumab has completed enrollment. Reporting of data is expected later this year or early 2024.
- Andreas Grauer, M.D. joined Omeros as chief medical officer. In this role, Dr. Grauer is responsible for guiding all clinical activities globally for the company, including clinical development and operations, medical affairs, safety, and biometrics. A highly tenured physician, scientist and pharmaceutical leader, Dr. Grauer brings to Omeros over 20 years of industry experience across a broad range of therapeutic areas.

"Having discontinued our Phase 3 ARTEMIS-IGAN trial, we are closely examining the data to learn what happened and why so that we can apply the findings to the design and conduct of future renal clinical studies across our complement franchise," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "Our primary focus is achieving regulatory approval and commercialization for our MASP-2 inhibitor narsoplimab to treat

TA-TMA patients and driving our MASP-3 inhibitor OMS906, believed to be the premier alternative pathway target and drug, into multiple Phase 3 programs and completing clinical development as quickly as possible. The upcoming presentations at ASH should help to focus others on the value of these programs – a TA-TMA approval will validate both narsoplimab and our other MASP-2 programs for which there are no predicates given Omeros' broad patent position, while the multiple indications already validated by other alternative pathway inhibitors deliver a roadmap and are accretive to OMS906 and our MASP-3 platform. We expect that Omeros has the financial runway to capitalize on value-driving milestones for these programs, and we intend to extend that runway further through cost-containment measures and other means. Having secured substantial funding from NIDA for OMS527 and with the potential to lever a relatively small investment into a large value across our immuno-oncology platforms, our pipeline of clinical and earlier-stage assets remains robust with multiple opportunities to grow shareholder value."

Third Quarter and Recent Clinical Developments

- Recent developments regarding narsoplimab, our lead monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 ("MASP-2"), include the following:
    - We continue to work towards the planned resubmission of our BLA for narsoplimab in TA-TMA. We have submitted to FDA a formal statistical plan for analysis of survival data available from an already-identified external source of TA-TMA patient data. In parallel, we continue to compile and revise the modules of our BLA for resubmission. Assuming favorable feedback on our formal plan for analysis of external survival data, we expect that the BLA could be completed and resubmitted within a timeframe that, allowing for the full FDA review period of six months, would result in FDA rendering an approval decision in mid-2024.
    - In October 2023, we announced preliminary results of the pre-specified interim analysis of our Phase 3 ARTEMIS-IGAN trial evaluating narsoplimab for the treatment of IgA nephropathy. Topline results showed that narsoplimab did not reach statistically significant improvement over placebo on the primary endpoint of reduction in proteinuria assessed by 24-hour urine protein excretion at 36 weeks in the intent-to-treat population of 180 IgA nephropathy patients with baseline proteinuria above 2 grams per day. Although the narsoplimab-treated group reported substantial proteinuria improvement, the proteinuria improvement in the placebo group was substantially greater than in reported Phase 3 clinical trials assessing other agents for IgA nephropathy. Based on the absence of a statistically significant improvement, and as previously agreed with FDA, the ARTEMIS-IGAN clinical trial has been discontinued.
    - An abstract detailing compassionate-use treatment with narsoplimab of 15 adult and pediatric patients with TA-TMA, 14 of whom had "high-risk" TA-TMA, has been accepted for presentation at the ASH annual meeting to be held in December 2023. The poster will be presented by Dr. Marta Castelli, Department of

Oncology and Hematology, University of Milan and Azienda Socio-Sanitaria Territoriale Papa Giovanni XXIII, Bergamo, Italy.

- A manuscript describing the pulmonary and central nervous system benefits of MASP-2 blockade on symptoms and survival in well-established animal models of COVID-19-related acute respiratory distress syndrome ("ARDS") was published in October in the Journal of Infectious Diseases. Discussions are ongoing with the U.S. Government regarding development of narsoplimab for use in severe COVID-19 and other forms of ARDS.

- Recent developments regarding OMS1029, our long-acting, next-generation MASP-2 inhibitor, include:
  - Dosing is completed in the first cohort of our ongoing Phase 1 multiple-ascending-dose ("MAD") study of OMS1029 in healthy subjects. In a single-ascending-dose Phase 1 clinical trial completed in early 2023, as in the ongoing MAD study, OMS1029 was well tolerated and no safety concerns were identified. Preliminary pharmacokinetic and pharmacodynamic ("PK/PD") data from that study showed dose-proportional exposure and sustained lectin pathway inhibition, consistent with once-quarterly intravenous or subcutaneous dosing. PK/PD data from the MAD study are expected in the first part of 2024. A Phase 2 program is slated to begin next summer in a larger market indication.

- Recent developments regarding OMS906, our lead monoclonal antibody targeting mannan-binding lectin-associated serine protease-3 ("MASP-3"), the key activator of the alternative pathway, include:
  - Enrollment has been completed in our Phase 2 clinical trial evaluating OMS906 in PNH patients who have had an unsatisfactory response to the C5 inhibitor ravulizumab. The study has a "switch-over" design and enrolls PNH patients receiving ravulizumab, adds OMS906 to provide combination therapy with ravulizumab for 24 weeks, and then provides OMS906 monotherapy in patients who demonstrate a hemoglobin response with combination therapy. Data are expected to be shared publicly later this year or early next.
  - Our clinical program evaluating OMS906 in patients with complement 3 glomerulopathy ("C3G") is also underway and is expected to begin enrolling C3G patients next month.
  - We have initiated an extension study to assess the long-term safety and tolerability of OMS906 in patients with PNH. Enrolled patients who have completed one of our two Phase 2 PNH studies evaluating OMS906 will move directly into the extension study without interruption of treatment. Data from this study will support a planned BLA for OMS906 in PNH.
  - Initiation of Phase 3 programs for OMS906 in PNH and C3G are targeted for the third quarter of 2024.
  - An abstract with new and updated data from our Phase 2 study of OMS906 in treatment-naive PNH patients has been accepted for podium presentation at the upcoming ASH annual meeting. The presentation describes the clinically meaningful and beneficial effects of OMS906 on hemoglobin with restoration of gender normal levels, on lactate dehydrogenase, and on red blood cell clone size in PNH patients.

- An abstract providing in vitro and in vivo mechanistic support for the clinical efficacy of OMS906 observed in treatment-naïve PNH patients will also be presented at the ASH annual meeting.
- To date across all clinical studies with OMS906, the drug has been well tolerated and has demonstrated no safety signals of concern.

- Recent developments regarding OMS527, our phosphodiesterase 7 ("PDE7") inhibitor program focused on addictions and compulsive disorders as well as movement disorders, include:
  - We continue to pursue development of our lead orally administered PDE7 inhibitor compound for the treatment of cocaine use disorder ("CUD"). This work was initiated at the request of, and is being performed in collaboration with, the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health. The development efforts are supported by a three-year, $6.69 million grant from NIDA and is intended to support a preclinical cocaine interaction study and a randomized, placebo-controlled, inpatient clinical study evaluating the safety and effectiveness of OMS527 in patients with CUD. We expect the preclinical interaction study to begin in early 2024. Previously, a Phase 1 clinical trial of the study drug in healthy subjects was successfully completed.
  - Together with collaborators at Emory University, we continue to evaluate the potential of our PDE7 inhibitors to treat levodopa-induced dyskinesias ("LID"). LID is caused by prolonged treatment with levodopa ("L-DOPA"), the most prescribed treatment for the over 10 million patients with Parkinson's disease worldwide. LID is reported to affect approximately 50 percent of Parkinson's patients who have been treated for five or more years with L-DOPA. The only approved treatment for LID is marginally effective and fraught with safety issues.

- Recent developments regarding OMIDRIA®, our former ophthalmologic product used in cataract surgery on which we receive royalties on worldwide net sales by Rayner Surgical include the following:
  - The Centers for Medicare and Medicaid Services ("CMS") issued its 2024 Hospital Outpatient Prospective Payment System final rule in October 2024. In that rule, CMS recommitted to separate payment for OMIDRIA in ambulatory surgery centers ("ASCs") throughout 2024. As mandated by Congress in this year's Consolidated Appropriations Act, CMS, beginning January 1, 2025, will separately pay for OMIDRIA in both hospital outpatient departments and in ASCs until at least January 1, 2028.

Financial Results

Net loss was $37.8 million in the quarter ended September 30, 2023, or $0.60 per share, compared to a net loss in the prior year quarter of $17.5 million, or $0.28 per share. The increase in the current year quarter net loss was primarily attributable to an incremental $18.9 million gain in discontinued operations in the prior year quarter due to remeasurement of the contract royalty asset. Excluding the incremental gain, net loss for the prior year quarter would have been $36.4 million. Net loss from continuing operations was $51.7 million in the current quarter compared to a net loss of $54.8 million in the prior year quarter. Cash burn for the quarter ending September 30,

2023 was $31.0 million.

For the nine months ended September 30, 2023, our net loss was $108.8 million, or $1.73 per share compared to $81.3 million, or $1.30 per share, in the prior year period. Net loss from continuing operations for the nine months ended September 30, 2023 was $135.6 million compared to a loss of $136.0 million in the prior year period.

For the third quarter of 2023, we earned OMIDRIA royalties of $10.0 million on Rayner Surgical's U.S. net sales of $33.3 million. This compares to earned royalties of $16.5 million during the third quarter of the prior year on U.S. net sales of $33.0 million. The difference in earned royalties reflects the decrease from 50 percent to 30 percent in the base royalty rate applicable to U.S. net sales of OMIDRIA, which occurred in December 2022 upon achievement of the $200.0 million milestone payment event. The royalty rate applicable to any sales outside the U.S. remains unchanged at 15 percent. Royalties are recorded as a reduction of the OMIDRIA contract royalty asset on our balance sheet.

Total costs and expenses for the third quarter of 2023 were $48.2 million compared to $50.8 million for the third quarter of 2022. The decrease was primarily due to reduction in clinical trial costs. This reduction was partially offset by increases in selling, general and administrative expenses.

Interest expense during the third quarter of 2023 was $7.9 million compared to $4.9 million during the prior year quarter. The increase was due to interest on our OMIDRIA royalty obligation associated with the sale of a portion of our OMIDRIA royalty receivables, an arrangement which we entered into at the end of September 2022.

During the third quarter of 2023, we earned $4.4 million in interest and other income compared to $0.9 million in the prior year quarter. The increase was due to higher average balances available to invest and higher market interest rates in the current year quarter.

Net income from discontinued operations, net of tax, was $13.9 million, or $0.22 per share, in the third quarter of 2023 compared to $37.3 million, or $0.59 per share, in the third quarter of 2022. The decrease in the current year quarter was primarily attributable to an incremental $18.9 million gain in discontinued operations in the prior year quarter due to the remeasurement of the contract royalty asset.

As of September 30, 2023, we had $310.3 million of cash and short-term investments, all of which are held in our name, available for operations and debt service.

On November 15, 2023, the $95.0 million outstanding on the 2023 unsecured convertible senior notes will become due. We anticipate retiring the notes at maturity with available cash and investments.

Conference Call Details

Omeros' management will host a conference call and webcast 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.

For online access to the live webcast of the conference call, go to Omeros' website at **https://investor.omeros.com/upcoming-events**.

To access the live conference call via phone, participants must register at **this link** to receive a unique PIN. Once registered, you will have two options: (1) Dial in to the conference line provided at the registration site using the PIN provided to you, or (2) choose the "Call Me" option, which will instantly dial the phone number you provide. Should you lose your PIN or registration confirmation email, simply re-register to receive a new PIN.

A replay of the call will be made accessible online at **https://investor.omeros.com/archived-events**.

About Omeros Corporation

Omeros is an innovative biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting immunologic disorders including complement-mediated diseases, cancers, and addictive and compulsive disorders. Omeros' lead MASP-2 inhibitor narsoplimab targets the lectin pathway of complement and is the subject of a biologics license application pending before FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. Omeros' long-acting MASP-2 inhibitor OMS1029 is currently in a Phase 1 multi-ascending-dose clinical trial. OMS906, Omeros' inhibitor of MASP-3, the key activator of the alternative pathway of complement, is advancing in clinical programs for paroxysmal nocturnal hemoglobinuria and complement 3 glomerulopathy. Funded by the National Institute on Drug Abuse, Omeros' lead phosphodiesterase 7 inhibitor OMS527 is in clinical development for the treatment of cocaine use disorder and, in addition, is being developed as a therapeutic for other addictions as well as for a major complication of treatment for movement disorders. Omeros also is advancing a broad portfolio of novel immuno-oncology programs comprised of two cellular and three molecular platforms. For more information about Omeros and its programs, visit **www.omeros.com**

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, including statements regarding the anticipated next steps in relation to the biologics license application for narsoplimab, the timing of regulatory events, the availability of clinical trial data, the prospects for obtaining FDA approval of narsoplimab in any indication, expectations regarding the initiation or continuation of clinical trials evaluating Omeros’ drug candidates and the anticipated availability of data therefrom, and expectations regarding the sufficiency of the Company’s capital resources to fund operations, 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, unanticipated or unexpected outcomes of regulatory processes in relevant jurisdictions, unproven preclinical and clinical development activities, the Company’s financial condition and results of operations, regulatory processes and oversight, challenges associated with manufacture or supply of our investigational or clinical products, 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 13, 2023. 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, whether as a result of new information, future events or otherwise, except as required by applicable law.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Costs and expenses:				
Research and development	$31,731	$38,568	$85,980	$86,172
Selling, general and administrative	16,422	12,198	38,785	37,079

Total costs and expenses	48,153	50,766	124,765	123,251
Loss from operations	(48,153)	(50,766)	(124,765)	(123,251)
Interest expense	(7,916)	(4,932)	(23,781)	(14,799)
Interest and other income	4,413	906	12,913	2,069
Net loss from continuing operations	(51,656)	(54,792)	(135,633)	(135,981)
Net income from discontinued operations, net of tax	13,906	37,336	26,888	54,665
Net loss	$(37,750)	$(17,456)	$(108,745)	$(81,316)
Basic and diluted net income (loss) per share:				
Net loss from continuing operations	$(0.82)	$(0.87)	$(2.16)	$(2.17)
Net income from discontinued operations	0.22	0.59	0.43	0.87
Net loss	$(0.60)	$(0.28)	$(1.73)	$(1.30)
Weighted-average shares used to compute basic and diluted net income (loss) per share	62,856,721	62,730,015	62,840,990	62,728,276

OMEROS CORPORATION
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEET
(In thousands)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 30,640	$ 11,009
Short-term investments	279,670	183,909
OMIDRIA contract royalty asset, short-term	29,228	28,797

Receivables	6,878	213,221
Prepaid expense and other assets	4,922	6,300
Total current assets	351,338	443,236
OMIDRIA contract royalty asset	119,502	123,425
Right of use assets	19,460	21,762
Property and equipment, net	1,717	1,492
Restricted investments	1,054	1,054
Total assets	$ 493,071	$ 590,969
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 5,866	$ 5,989
Accrued expenses	34,859	30,551
Current portion of unsecured convertible senior notes, net	94,909	94,381
Current portion of OMIDRIA royalty obligation	6,654	1,152
Current portion of lease liabilities	4,888	4,310
Total current liabilities	147,176	136,383
Unsecured convertible senior notes, net	221,828	220,906
OMIDRIA royalty obligation	118,770	125,126
Lease liabilities, non-current	19,249	22,426
Other accrued liabilities, non-current	—	444
Shareholders' equity (deficit):		
Common stock and additional paid-in capital	730,510	721,401
Accumulated deficit	(744,462)	(635,717)
Total shareholders' equity (deficit)	(13,952)	85,684
Total liabilities and shareholders' equity (deficit)	$ 493,071	$ 590,969

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