# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): November 9, 2020**

# OMEROS CORPORATION
**(Exact name of Registrant as Specified in Its Charter)**

| **Washington** | **001-34475** | **91-1663741** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |
| **201 Elliott Avenue West Seattle, WA** | | **98119** |
| **(Address of Principal Executive Offices)** | | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (206) 676-5000**

**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities Registered Pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common stock, $0.01 par value per share | OMER | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 2.02 Results of Operations and Financial Condition.**

On November 9, 2020, Omeros Corporation issued a press release announcing financial results for the three and nine months ended September 30, 2020. A copy of such press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the United States Securities and Exchange Commission made by Omeros Corporation, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release, dated November 9, 2020, pertaining to Omeros Corporation's financial results for the three and nine months ended September 30, 2020. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**OMEROS CORPORATION**

Date: November 9, 2020

By: /s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D.
President, Chief Executive Officer and
Chairman of the Board of Directors

**Omeros Corporation Reports Third Quarter 2020 Financial Results**

**SEATTLE, WA – November 9, 2020 –** 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, 2020, which include:

- Revenues for the third quarter of 2020 were $26.1 million following an $8.7 million deduction as a return reserve associated with the expiration of pass-through reimbursement for OMIDRIA on October 1, 2020. Omeros believes that it qualifies for and is pursuing separate payment from the Centers for Medicare and Medicaid Services (CMS) for OMIDRIA. For comparison, third quarter 2019 and second quarter 2020 revenues were $29.9 million and $13.5 million, respectively.

- Net loss in the third quarter of 2020 was $38.5 million, or $0.66 per share, of which $13.6 million, or $0.23 per share, were non-cash expenses. This compares to a net loss of $16.5 million, or $0.33 per share, in the third quarter of 2019. On a non-GAAP basis, adjusted net loss for the third quarter of 2020 was $19.9 million, or $0.34 per share, after excluding non-cash expenses and a $5.0 million technology access fee. Net loss and adjusted net loss include the $8.7 million deduction in third quarter 2020 revenues for the return reserve.

- At September 30, 2020, the company had cash, cash equivalents and short-term investments available for operations of $153.5 million. This includes $93.7 million in proceeds from a common stock offering and $76.9 million in proceeds from the issuance of convertible notes, following the use of a portion of the proceeds to repurchase a portion of our previously outstanding convertible notes and enter into certain derivative transactions, all of which took place during the third quarter.

- Omeros will complete submission next week to the U.S. Food and Drug Administration (FDA) of its rolling Biologics License Application (BLA) for narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA or TA-TMA). Final clinical data from the BLA were presented in a webcast last month, as described below.

- In August, Omeros reported results from a study evaluating narsoplimab for treatment of COVID-19-associated acute respiratory distress syndrome (ARDS). Six COVID-19 patients in Bergamo, Italy were treated with narsoplimab. All six patients required mechanical ventilation prior to narsoplimab treatment, and each recovered, survived and was discharged from the hospital following treatment. Two historical control groups that had similar baseline characteristics showed mortality rates of 32 percent and 53 percent. The results of the trial were published in the peer-reviewed journal *Immunobiology*. Five to six months after cessation of narsoplimab dosing, all patients were doing well and none showed clinical or laboratory evidence of longer-term effects from COVID-19.

- In September, Omeros initiated its Phase 1 clinical trial for OMS906, the company's MASP-3 inhibitor targeting the alternative pathway, and has completed dosing in the first patient cohort.

"The final clinical study results for narsoplimab in the treatment of transplant-associated TMA speak for themselves. The non-clinical and CMC sections of the BLA are under review by FDA, and the clinical sections, which will be submitted next week, are complete, comprehensive and compelling," said Gregory A. Demopulos, M.D., Omeros' chairman and chief executive officer. "In anticipation of priority review, our team is readying for a successful commercial launch.

Beyond TA-TMA and its Phase 3 trials in IgA nephropathy and aHUS, narsoplimab is increasingly recognized as a likely answer to severe COVID-19. Our complement franchise continues expanding with our MASP-3 inhibitor OMS906 on course and marching through its Phase 1 program. Confident that OMIDRIA qualifies for separate payment from CMS, we expect that the drug will increasingly support our unique portfolio of complement inhibitors and the rest of our exciting pipeline programs. Developing a life-saving drug is a rare opportunity, and all of us at Omeros are energized and inspired by the patients – children and adults – who are alive today because of our team's efforts."

**Third Quarter and Recent Developments**

- Recent developments regarding narsoplimab, Omeros' lead fully human monoclonal antibody targeting 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, Professor Alessandro Rambaldi of the University of Milan and Papa Giovanni XXIII Hospital and Dr. Miguel Perales of Memorial Sloan Kettering Cancer Center presented the final efficacy and safety data from the pivotal trial of narsoplimab in the treatment of HSCT-TMA, which form the basis of the clinical sections of the rolling BLA.
        - The complete response rates of 61 percent in patients receiving at least one dose of narsoplimab (the full analysis set) and 74 percent in patients receiving the protocol-specified narsoplimab treatment of at least four weeks (the per-protocol population) are higher than what was previously reported.
        - Median overall survival was 274 days in the full analysis set, 361 days in the per-protocol population and could not be estimated for complete responders because more than half of the responders were still alive at last follow-up, out to as long as roughly four years following treatment.
    - Omeros applied to the Centers for Disease Control and Prevention (CDC) for an International Classification of Diseases (ICD-10) diagnosis code for HSCT-TMA, and CDC has preliminarily indicated its support for the diagnosis code. Omeros also applied to CMS for an ICD-10 procedure code for the administration of narsoplimab, and CMS has indicated its support for issuance of the procedure code.
    - In addition to the six COVID-19 patients who were treated with narsoplimab, Omeros has continued to treat critically ill COVID-19 patients under compassionate use. Omeros has also received requests and is in discussions to include narsoplimab in platform trials for COVID-19.
    - Omeros' discussions regarding the use of narsoplimab in COVID-19 have progressed with leadership across BARDA, NIAID, NCAT and NIH regarding narsoplimab for the treatment of critically ill COVID-19 patients. With COVID-19 surging again globally and other therapeutics having failed to show benefit in critically ill COVID-19 patients, there is increasing focus on narsoplimab.
- Recent developments regarding OMIDRIA include the following:
    - Pass-through reimbursement status for OMIDRIA expired on October 1, 2020. Omeros met with CMS and the Department of Health and Human Services to assert that OMIDRIA meets the objective criteria specified by CMS and must be paid separately in the ambulatory surgery center (ASC) setting. Omeros also submitted to CMS a comment letter on the proposed 2021 Outpatient Prospective Payment System/ASC Rule along with a legal memorandum from an outside law firm reiterating this position and seeking confirmation of separate payment status for OMIDRIA in the ASC setting for the fourth quarter of 2020 and calendar year 2021.
    - An article entitled "Real-world opioid prescribing after cataract surgery among patients who received intracameral phenylephrine and ketorolac 1.0%/0.3%" was published in the peer-reviewed journal *Current Medical Research and Opinion*. The study demonstrates that patients who received OMIDRIA during cataract surgery were prescribed fewer opioid pills following surgery than patients who did not

receive OMIDRIA, despite the OMIDRIA-treated group having a greater incidence of preoperative comorbidities and higher risk for surgical complexity.

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

    - Omeros has completed, on schedule, dosing in the first cohort in a Phase 1, placebo-controlled, double-blind, single-ascending-dose and multiple-ascending-dose study for OMS906, the company's MASP-3 inhibitor. The second cohort in the Phase 1 study has begun dosing. Omeros expects to achieve a once-monthly subcutaneous dosing regimen. Data readout from the Phase 1 study is planned for next year.

    - Omeros presented data on the OMS906 program at the 4th Complement-based Drug Development Summit in October.

**Financial Results**

For the third quarter of 2020, OMIDRIA revenues were $26.1 million, down from $29.9 million for the same period in 2019 and up from $13.5 million for the second quarter of 2020. The decrease compared to the third quarter of 2019 was due to an $8.7 million deduction as a reserve for product returns related to the expiration of pass-through reimbursement on October 1, 2020.

Total costs and expenses for the third quarter of 2020 were $51.5 million compared to $41.0 million for the same period in 2019. The increase reflects a fee payable under a technology license agreement related to Omeros' MASP-3 program and increased pre-commercialization marketing activities for narsoplimab. Selling, general and administrative expenses were $19.8 million in the third quarter of 2020, compared to $16.9 million in the corresponding period in 2019.

For the three months ended September 30, 2020, Omeros reported a net loss of $38.5 million, or $0.66 per share, compared to a net loss of $16.5 million, or $0.33 per share, for the same period in 2019. On a non-GAAP basis, adjusted net loss for the three months ended September 30, 2020 was $19.9 million, or $0.34 per share, after excluding non-cash expenses of $13.6 million, or $0.23 per share, and a technology access fee of $5.0 million, or $0.09 per share. Both net loss and adjusted net loss include the $8.7 million deduction in the third quarter of 2020 for the return reserve.

As of September 30, 2020, Omeros had $153.5 million of cash, cash equivalents and short-term investments available for operations and accounts receivable of $37.4 million.

During the third quarter, Omeros issued approximately $225.0 million aggregate principal amount 5.25% convertible senior notes due February 2026 (the 2026 Notes). Concurrently, Omeros repurchased $115.0 million aggregate principal amount of previously outstanding 6.25% convertible senior notes due November 2023. Omeros recorded a $13.4 million non-cash loss on early extinguishment of debt and a $7.9 million non-cash income tax benefit associated with these transactions. Omeros also entered into capped call contracts associated with the 2026 Notes that cover, subject to anti-dilution adjustments that may not match those applicable to the conversion price of the 2026 Notes, the number of shares of Omeros' common stock underlying the 2026 Notes when Omeros' common stock is trading between the initial conversion price of approximately $18.49 and the $26.10 cap price.

In August, Omeros sold 6.9 million shares in an underwritten public offering and received $93.7 million in net proceeds from the offering.

**About Omeros Corporation**

Omeros is a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting inflammation, complement-mediated diseases, disorders of the central nervous system and immune-related diseases, including cancers. Its commercial product OMIDRIA (phenylephrine and ketorolac intraocular solution) 1%/0.3% continues to gain market share in cataract surgery. Omeros' lead MASP-2 inhibitor narsoplimab targets the lectin pathway of complement and is the subject of a rolling biologics license application for hematopoietic stem cell transplant-associated thrombotic microangiopathy. Narsoplimab is also in multiple late-stage clinical development programs focused on other complement-mediated disorders, including IgA nephropathy, atypical hemolytic uremic syndrome and COVID-19. Omeros' MASP-3

inhibitor OMS906, which targets the complement system's alternative pathway, recently entered the clinic, and the company's PDE7 inhibitor OMS527 has successfully completed Phase 1. Omeros' pipeline holds a diverse group of preclinical programs including a novel antibody-generating technology and a proprietary GPCR platform through which it controls 54 new GPCR drug targets and their corresponding compounds. One of these novel targets, GPR174, modulates a new cancer immunity axis recently discovered by Omeros, and the company is advancing small-molecule GPR174 inhibitors.

**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, the impact of COVID-19 on our business, financial condition and results of operations, 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 (SEC) on March 2, 2020, as supplemented by our Quarterly Reports on Form 10-Q filed with the SEC and subsequent filings with the SEC. 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.

**Non-GAAP Information**

This press release includes financial measures that are not calculated in accordance with U.S. generally accepted accounting principles (GAAP). To supplement Omeros' consolidated financial statements presented in accordance with GAAP, Omeros is presenting adjusted net loss and adjusted net loss per share, which are non-GAAP financial measures. Adjusted net loss consists of GAAP net loss excluding non-cash expenses and a technology access fee.

Omeros believes that the presentation of these non-GAAP financial measures provides important supplemental information to investors regarding financial trends relating to Omeros' results of operations and facilitates comparisons of the company's core operating performance against prior periods. The non-GAAP measures should be considered supplemental to, and not a substitute for or superior to, financial measures calculated in accordance with GAAP because non-GAAP financial measures used in this press release have limitations in that they do not reflect all costs associated with the operations of Omeros' business. In addition, these measures may be different from, and therefore not comparable to, similarly titled measures used by other companies. The accompanying table provides more detail on the GAAP financial measures that are most directly comparable to the non-GAAP financial measures described above and the related reconciliations between these financial measures.

**Contact**:

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**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, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Revenue: | | | | |
| Product sales, net | $ 26,114 | $ 29,856 | $ 63,181 | $ 78,389 |
| | | | | |
| Costs and expenses: | | | | |
| Cost of product sales | 401 | 278 | 815 | 464 |
| Research and development | 31,316 | 23,746 | 84,359 | 69,108 |
| Selling, general and administrative | 19,825 | 16,933 | 54,792 | 48,493 |
| Total costs and expenses | 51,542 | 40,957 | 139,966 | 118,065 |
| Loss from operations | (25,428) | (11,101) | (76,785) | (39,676) |
| Loss on early extinguishment of debt | (13,374) | — | (13,374) | — |
| Interest expense | (6,882) | (5,715) | (18,763) | (16,846) |
| Other (expense) income | (633) | 353 | 280 | 1,261 |
| Loss before income taxes | (46,317) | (16,463) | (108,642) | (55,261) |
| Income tax benefit | 7,854 | — | 7,854 | — |
| Net loss | $ (38,463) | $ (16,463) | $ (100,788) | $ (55,261) |
| Comprehensive loss | $ (38,463) | $ (16,463) | $ (100,788) | $ (55,261) |
| Basic and diluted net loss per share | $ (0.66) | $ (0.33) | $ (1.81) | $ (1.12) |
| Weighted-average shares used to compute basic and diluted net loss per share | 58,233,988 | 49,373,156 | 55,682,379 | 49,157,055 |

**OMEROS CORPORATION**
**UNAUDITED CONSOLIDATED BALANCE SHEET DATA**
**(In thousands)**

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| Cash, cash equivalents and short-term investments | $ 153,523 | $ 60,788 |
| Working capital | 148,266 | 48,286 |
| Restricted investments | 1,154 | 1,154 |
| Total assets | 227,075 | 136,969 |
| Total current liabilities | 47,719 | 55,459 |
| Lease liabilities | 33,471 | 35,822 |
| Unsecured convertible senior notes, net | 232,808 | 158,213 |
| Accumulated deficit | (835,399) | (734,611) |
| Total shareholders' deficit | (87,326) | (109,021) |

**RECONCILIATION OF**
**ADJUSTED NET LOSS AND ADJUSTED NET LOSS PER SHARE**
**TO NET LOSS AND EARNINGS PER SHARE**
**(In thousands, except per share data)**

| | Three Months Ended September 30, 2020 | |
|---|---|---|
| | Reported Amount | Per Share |
| GAAP net loss | $ (38,463) | $ (0.66) |
| Non-cash expenses: | | |
| Stock-based compensation expense | 3,824 | 0.07 |
| Non-cash interest expense | 3.010 | 0.05 |
| Depreciation and amortization | 404 | 0.01 |
| Loss on early extinguishment of debt | 13,374 | 0.23 |
| Fair value settlement upon termination of cap call contract | 838 | 0.01 |
| Income tax benefit | (7,854) | (0.13) |
| Technology license fee | 5,000 | 0.19 |
| Adjusted net loss | $ (19,867) | $ (0.34) |