OMEROS®

OMEROS CORPORATION

2023 ANNUAL REPORT

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LET SCIENCE LEAD THE WAY®

April 29, 2024

Dear Fellow Shareholders:

For Omeros, 2023 was a year of significant development progress and financial strengthening marred by a failed Phase 3 clinical trial in IgA nephropathy. Despite that disappointment, Omeros is stronger today than it has ever been.

The outcome of our narsoplimab Phase 3 clinical trial in IgAN was an unwelcome surprise. In addition to a large placebo effect, the dosing regimen for a good number of the trial's patients appears to have been suboptimal. The information gained from that trial better informs not only our work with narsoplimab but across all our MASP-2/lectin pathway (LP) inhibitor programs. On the TA-TMA front, analysis of 136 patients in our narsoplimab expanded access program shows strong overall survival (median 461 days following TMA diagnosis) similar to that of our pivotal clinical trial. Of those 136 adult and pediatric patients, 53 had failed or stopped previous treatment regimens with one or more of eculizumab, ravulizumab, defibrotide and/or pegcetacoplan yet, with narsoplimab, 49% achieved 1-year survival from date of TMA diagnosis and 64% reached 1-year survival from date of transplant. The drug is saving lives. With over 600-subject exposure and no observed safety signal of concern, the benefit-risk profile is clearly favorable. Interactions with FDA regarding resubmission of our BLA are ongoing and we remain committed to achieving approval of narsoplimab in TA-TMA.

We continue making tremendous progress with OMS906, our lead antibody targeting MASP-3 and the alternative pathway (AP) of complement, and the steady stream of data are consistent and impressive. Based on ongoing market research focus groups with providers, OMS906 is planned for once-every-2-months to once-quarterly dosing and offers a differentiated profile from other AP inhibitors. Two OMS906 Phase 2 clinical trials in PNH – one in treatment-naïve patients and the other in patients with a suboptimal response to ravulizumab – are fully enrolled and each has reported data at least as strong as any other AP-targeting agent on the market or in development. A long-term extension study of OMS906 in PNH, planned to support a future marketing application, is underway. A Phase 3 program in PNH is expected to begin late this year and a Phase 3 program in C3 glomerulopathy is targeted for early 2025. The clinical evidence points to significant potential compliance/efficacy and safety advantages of OMS906 over other marketed and developing AP inhibitors. Novartis' iptacopan, a twice-daily oral Factor B inhibitor, continues to diagram the roadmap of indications (including most recently IgAN) for us to follow with what we believe is a better target in MASP-3 and a better drug in OMS906 – all of which progressively and substantially inure value to our OMS906 program.

OMS1029, our long-acting second-generation MASP-2 antibody, is wrapping up Phase 1 development. Well-tolerated without any safety signal of concern, the pharmacokinetic/pharmacodynamic data support low-volume once-quarterly subcutaneous or intravenous dosing. Convenient dosing with effectively complete LP inhibition should make OMS1029 an attractive first-in-class therapeutic for LP-related large-market chronic indications, several of which we are evaluating for Phase 2 development. Our orally available MASP-2 small-molecule and MASP-3

small-molecule programs are also rapidly advancing.

Beyond our premier complement franchise, we have made significant strides within our portfolio of earlier-stage development programs. In April 2023, the National Institute on Drug Abuse awarded us a 3-year $6.7 million grant to develop OMS527, our lead orally administered phosphodiesterase-7 inhibitor, for treatment of cocaine use disorder. Through this initial funding, OMS527 – designed to treat the breadth of substance use disorders with significant and well-recognized potential advantages over other current anti-addictive therapies – is slated for evaluation in a randomized placebo-controlled clinical trial evaluating its safety and effectiveness in patients with cocaine use disorder.

Our 5 novel cellular and biologic immuno-oncology platforms are generating a nearly constant flow of positive *in vitro, ex vivo* and animal data, contributing to our broad and growing intellectual property estate. Unique in their collective approaches – targeting both cell-surface and intracellular cancer targets for broad cancer applicability, designed to increase both CD4 and CD8 levels to mitigate loss of treatment effect seen with other therapies like checkpoint inhibitors, no need for costly and time-intensive cellular modification or engineering, and creation of immune memory against future relapse – we and experts in the field are excited by what we are seeing and by our immuno-oncology program's prospects.

Underpinning all these programmatic accomplishments is the strong financial foundation that Omeros continues resolutely building. Since its December 2021 strategic divestiture to Rayner Surgical, OMIDRIA® has provided us with nearly $700 million in non-dilutive operating capital, including receipt in 2023 of a $200 million milestone payment along with more than $33 million in royalties on OMIDRIA net sales and, earlier this year, another $116 million upfront payment tied to expansion of our existing royalty monetization arrangement with the potential to earn an additional $55 million in milestone payments. Further enhancing shareholder value, we reduced our outstanding common share count by 8 percent through stock repurchases. Following retirement of the 2023 convertible notes ($95 million in full), with approximately $230 million in cash and investments at March 31, 2024, our operating runway now extends into 2026.

I hope that the foregoing provides a better understanding of our accomplishments in 2023. Taken together, I believe our progress last year demonstrates possession of the foresight and resilience needed to navigate setbacks, to deliver on the promise of our science, to generate value for our shareholders and, above all, to improve the lives of the patients to whom our efforts are devoted.

On behalf of our board of directors and employees, I thank you for your continued support.

Sincerely,

Gregory A. Demopulos, M.D.
Chairman & Chief Executive Officer

FORM 10-K
2023

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to

Commission file number: 001-34475

OMEROS CORPORATION

(Exact name of registrant as specified in its charter)

Washington	**91-1663741**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

201 Elliott Avenue West
Seattle, Washington 98119
(Address of principal executive offices and zip code)

(206) 676-5000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	OMER	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was $328,153,747.

As of March 28, 2024, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 57,942,695.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement with respect to the 2024 Annual Meeting of Shareholders, which is to be filed pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Form 10-K.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), which are subject to the "safe harbor" created by those sections for such statements. Forward-looking statements are based on our management's beliefs and assumptions and on currently available information. All statements other than statements of historical fact are "forward-looking statements." Terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "likely," "may," "plan," "possible," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

- our estimates of future operating expenses and projections regarding how long our existing cash, cash equivalents and short-term investments will fund our anticipated operating expenses, capital expenditures and debt service obligations;
- our ability to raise additional capital through the capital markets or one or more future equity offerings, debt financings, industry collaborations, licensing arrangements, asset sales or other means;
- our expectations regarding amounts potentially payable to us based on sales of our former commercial ophthalmology product OMIDRIA®;
- our expectations regarding clinical plans and anticipated or potential paths to regulatory approval of narsoplimab by the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA") in hematopoietic stem cell transplant-associated thrombotic microangiopathy ("TA-TMA"), COVID-19 or any other indication;
- whether and when our biologics license application ("BLA") for narsoplimab in TA-TMA may be resubmitted to FDA, whether and when a marketing authorization application ("MAA") may be submitted to the EMA for narsoplimab in any indication, and whether and when the FDA, the EMA or any other regulatory authority will grant approval for narsoplimab in any indication;
- our plans for the commercial launch of narsoplimab following any regulatory approval and our estimates and expectations regarding coverage and reimbursement for any approved products;
- our expectation that our contract manufacturer will manufacture narsoplimab when needed to support any regulatory filing and, if approved, to support commercial sale;
- our expectations regarding the clinical, therapeutic and competitive benefits and importance of our drug candidates;
- our ability to design, initiate and/or successfully complete clinical trials and other studies for our drug candidates and our plans and expectations regarding our ongoing or planned clinical trials;
- our expectations regarding: our ability to recruit and enroll patients in any ongoing or planned clinical trial; whether we can capitalize on the financial and regulatory incentives provided by orphan drug designations granted by the FDA, the European Commission ("EC"), or the EMA; and whether we can utilize the opportunities for expedited development and review that may be provided by fast-track or breakthrough therapy designations granted by FDA;
- our expectations about the commercial competition that our drug candidates, if commercialized, face or may face;
- our involvement in existing or potential claims, legal proceedings and administrative actions, and the merits, potential outcomes and effects of both existing and potential claims, legal proceedings and administrative actions, as well as regulatory determinations, on our business, prospects, financial condition and results of operations;
- the extent of protection that our patents provide and that our pending patent applications will provide, if patents are issued from such applications, for our technologies, programs, and drug candidates;
- the factors on which we base our estimates for accounting purposes and our expectations regarding the effect of changes in accounting guidance or standards on our operating results; and
- our expected financial position, performance, revenues, growth, costs and expenses, magnitude of net losses and the availability of resources.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item 1A of Part I of this Annual Report on Form 10-K under the heading "Risk Factors" and in Item 7 of Part II under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our other filings with the Securities and Exchange Commission ("SEC"). Given these risks, uncertainties and other factors, actual results or anticipated developments may not be realized or, even if substantially realized, they may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements, which represent our estimates and assumptions only as of the date of the filing of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable law, including the securities laws of the United States and the rules and regulations of the SEC, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

SUMMARY RISK FACTORS

The risk factors described below are a summary of the principal risk factors associated with an investment in our company. These are not the only risks we face. You should carefully consider the risk factors discussed in this summary, as well as the risk factors described in Item 1A. of this Annual Report on Form 10-K.

Risks related to our drug candidates, programs and operations include, but are not limited to, the following:

- inability to raise capital when needed;
- that our drug candidates may not successfully complete clinical development or be suitable for successful commercialization or generation of revenue;
- failure to obtain and maintain regulatory approval for marketing of future commercial products in the U.S. or in foreign jurisdictions;
- lack of adequate coverage or reimbursement from government and/or private payers for OMIDRIA or any of our drug candidates that we commercialize in the future;
- whether and to what extent future royalty and milestone payments that we are eligible to receive based on net sales of OMIDRIA by Rayner Surgical Inc. ("Rayner") will become payable;
- unpredictability of our operating results;
- any failure to comply with current or future government regulations;
- lack of internal manufacturing capacity and reliance on third parties;
- inability to acquire ingredients, excipients, test kits and other materials to manufacture our drug candidates on commercially reasonable terms;
- delays, suspensions or terminations of our clinical trials or clinical protocols;
- substantial costs as a result of commercial disputes, claims, litigation or other legal proceedings;
- inability to protect our intellectual property and proprietary technologies;
- our indebtedness and liabilities, which could limit the cash flow available for our operations;
- products developed by our competitors, which may diminish or eliminate the success of any products that we may commercialize;
- reliance on members of our management team and our ability to recruit and retain key personnel;
- reliance on third parties to conduct portions of our preclinical research and clinical trials; and
- the impact of our share repurchase program on our stock price.

General risks related to our business include the following:

- cyber-attacks or failures in telecommunications or other information technology systems;
- volatility of our stock price;
- dilution to our existing shareholders if we issue additional shares of our common stock or other securities that may be convertible into, or exercisable for, our common stock;
- adverse effects of natural disasters or other events on us or the third parties on whom we rely; and
- the impact of anti-takeover provisions in our charter documents and under Washington law on potential acquisitions of our company.

OMEROS CORPORATION
ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2023

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PART I

This Annual Report on Form 10-K contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this Annual Report. Please refer to the special note regarding forward-looking statements at the beginning of this Annual Report on Form 10-K for further information.

ITEM 1. BUSINESS

Overview

Omeros Corporation ("Omeros," the "Company" or "we") is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting immunologic diseases, including complement-mediated diseases and cancers related to dysfunction of the immune system, as well as addictive and compulsive disorders.

Complement-targeted Therapeutic Development Programs

We are advancing multiple development programs focused on diseases and disorders associated with the complement system, a group of specialized proteins that protect against invasive pathogens as well as damaged cells inside the body and comprise an important part of the body's immune system. When triggered, the various components of complement cooperate to generate an immune response that fights infection and clears damaged or dead cells, maintaining healthy function of the body's systems. However, dysregulation of the complement system (i.e., over- or under-activation) can be harmful and is associated with increased vulnerability to infections and non-infectious diseases, including autoimmune disorders, chronic inflammation, thrombotic microangiopathy, and cancer.

There are three distinct pathways of complement, each activated via one or more unique mechanisms:

- Classical pathway: activated by antigen-antibody complexes
- Lectin pathway: activated by lectin binding of carbohydrate patterns on the surfaces of damaged cells and microbes
- Alternative pathway: constitutively active and amplifies classical and lectin pathway activation

Our complement-targeted therapeutic development programs are primarily focused on diseases and disorders associated with the lectin and/or alternative pathways of complement. Our lectin pathway program includes inhibitors of mannan-binding lectin-associated serine protease 2 ("MASP-2") and our alternative pathway program includes inhibitors of mannan-binding lectin-associated serine protease 3 ("MASP-3").

Narsoplimab (OMS721), the lead candidate in our lectin pathway program, is a proprietary, patented human monoclonal antibody inhibitor of MASP-2, the key effector enzyme of the lectin pathway. Clinical development of narsoplimab is currently focused primarily on hematopoietic stem cell transplant-associated thrombotic microangiopathy ("TA-TMA"). We are also developing OMS1029, a long-acting, next-generation antibody and an orally administered small molecule targeting MASP-2 and the lectin pathway.

The lead drug candidate in our development program focused on the alternative pathway of complement is OMS906, a proprietary, patented monoclonal antibody targeting MASP-3. MASP-3 is the key activator of the alternative pathway of complement. We believe OMS906 has the potential to treat a wide range of alternative pathway-related diseases and that its attributes favorably differentiate OMS906 from other marketed and in-development alternative pathway inhibitors. Clinical development of OMS906 is currently ongoing in multiple alternative pathway-related disorders, including complement 3 glomerulopathy ("C3G"), a rare chronic kidney disease, and paroxysmal nocturnal hemoglobinuria ("PNH"), a rare and life-threatening hemolytic blood disorder. An orally administered small molecule MASP-3 inhibitor is also in development.

Other Development Programs

Our development pipeline also includes OMS527, our phosphodiesterase 7 ("PDE7") inhibitor program focused on addiction and movement disorders. We also have a diverse group of preclinical programs, including five immuno-oncology platforms directed to development of novel adoptive T cell/CAR-T therapies, immunomodulators, immunotoxins and cancer vaccines.

OMIDRIA Sale and Royalty Monetization Transactions

We previously developed and commercialized OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%, which is approved 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. We marketed OMIDRIA in the United States (the "U.S.") from the time of its commercial launch in 2015 until December 2021.

On December 23, 2021, we sold OMIDRIA and certain related assets, including inventory and prepaid expenses to Rayner Surgical Inc. ("Rayner") pursuant to an Asset Purchase Agreement, dated December 1, 2021 (the "Asset Purchase Agreement"). Under the Asset Purchase Agreement, Rayner paid us $126.0 million in cash at the closing and we retained all outstanding accounts receivable, accounts payable, and accrued expenses as of the closing date. Rayner is also obligated under the Asset Purchase Agreement to pay us royalties based on Rayner's net sales of OMIDRIA for a term that extends for the life of the patents covering OMIDRIA in the relevant jurisdiction. The latest expiration of a patent covering OMIDRIA in the United States is currently in 2035. Also pursuant to the Asset Purchase Agreement, we were entitled to receive a milestone payment of $200.0 million (the "Milestone Payment") within 30 days following an event (the "Milestone Event") that establishes separate payment for OMIDRIA for a continuous period of at least four years when furnished in the ambulatory surgery center ("ASC") setting. The Milestone Event occurred in December 2022 and we recorded a $200.0 million milestone receivable. We received the Milestone Payment together with accrued interest in February 2023.

On September 30, 2022, we entered into a Royalty Purchase Agreement (the "Original Agreement") with DRI Healthcare Acquisitions LP ("DRI") under which we received $125.0 million in cash in exchange for a portion of our royalties on global net sales of OMIDRIA payable by Rayner between September 1, 2022 and December 31, 2030, subject to certain annual caps on the royalty amounts payable to DRI, with Omeros entitled to receive all royalties paid in excess of the applicable caps.

On February 1, 2024, we entered into an amended and restated royalty purchase agreement (the "Amendment") with DRI to effect the sale to DRI of an expanded interest in the OMIDRIA royalties. The Amendment eliminated the annual caps on royalty payments to which DRI is entitled and provides that DRI will now receive all royalties on U.S. net sales of OMIDRIA payable between January 1, 2024 and December 31, 2031. We received $115.5 million in cash upon closing of the Amendment. Additionally, we are eligible under the Amendment to receive two milestone payments of up to $27.5 million each, payable in January 2026 and January 2028, respectively, based on achievement of certain thresholds for U.S. net sales of OMIDRIA. DRI is entitled to payment only to the extent of royalty payments that are payable on U.S. net sales of OMIDRIA on or before December 31, 2031 and DRI has no recourse to our assets other than its interest in the OMIDRIA royalties. Omeros retains the right to receive all royalties payable by Rayner on any net sales of OMIDRIA outside the U.S. payable from and after January 1, 2024, as well as all royalties on global net sales of OMIDRIA payable from and after December 31, 2031.

As discussed above, the term for royalty payments under the Asset Purchase Agreement expires based on the last-expiring OMIDRIA-related patent in the relevant country, which in the United States currently extends into 2035. The royalty rate payable by Rayner on net sales of OMIDRIA is currently 30% in the United States and 15% outside the U.S. These royalty rates are subject to reduction upon the occurrence of certain events described in the Asset Purchase Agreement. For example, the applicable U.S. royalty rate would be reduced to 10% during any specific period in which OMIDRIA is no longer eligible for separate payment (i.e., included in the packaged payment rate for the surgical procedure) under Medicare Part B. Pursuant to legislation enacted in late 2022, we expect separate payment for OMIDRIA under Medicare Part B to extend until at least January 1, 2028.

Our Drug Candidates and Development Programs

Our clinical drug candidates consist of the following:

Drug Candidate/Program	Targeted Disease(s)	Development Status	Next Expected Milestone
Narsoplimab (MASP-2 / Lectin Pathway)	Hematopoietic stem-cell transplant-associated thrombotic microangiopathy (TA-TMA)	Pivotal trial complete; CRL received; working with FDA on BLA resubmission	BLA resubmission
Narsoplimab (MASP-2 / Lectin Pathway)	Severe COVID-19, post-acute sequelae of SARS-CoV-2 infection (PASC, i.e., long COVID) and other causes of acute respiratory distress syndrome (ARDS)	Phase 2 trial in severe COVID-19 completed	Continue development of narsoplimab and diagnostic for lectin pathway hyperactivation for COVID-19/ARDS and related indications
OMS1029 (MASP-2 / Lectin Pathway)	Long-acting second-generation antibody targeting lectin pathway disorders	Phase 1 trial nearly complete (dosing completed and follow-up ongoing)	Select indication for Phase 2 development
OMS906 (MASP-3 / Alternative Pathway)	Paroxysmal nocturnal hemoglobinuria (PNH), complement 3 glomerulopathy (C3G) and other alternative pathway disorders	Phase 2	Complete Phase 2 trials with treated patients moving to extension study of long-term efficacy and finalize dose selections; Initiate pivotal Phase 3 clinical trials.
OMS527 (PDE7)	Addictions and compulsive disorders; movement disorders	Phase 1	Continue NIDA-funded research through completion of a Phase 1 cocaine interaction study and Phase 2 clinical trial in patients with cocaine use disorder; Determine whether and how best to continue development of OMS527 in levodopa-induced dyskinesia (LID).

Our pipeline of preclinical development programs includes the following:

Preclinical Program	Targeted Disease(s)	Development Status	Next Expected Milestone
MASP-2: small-molecule inhibitors	Lectin pathway disorders	Preclinical	Continue IND-enabling studies of current drug development candidate
MASP-3: small-molecule inhibitors	Alternative pathway disorders	Preclinical	Identify drug development candidate for clinical trials
Adoptive T-Cell and Chimeric Antigen Receptor (CAR) T-Cell Therapies	Wide range of cancers	Preclinical	Complete preclinical proof of concept studies and evaluate data
Immunomodulators/Immunotoxins/Cancer Vaccines	Wide range of cancers	Preclinical	Complete preclinical proof of concept studies and evaluate data

Complement Inhibitor Programs

The complement system plays a role in the body's inflammatory response and becomes activated as a result of tissue damage or trauma or microbial pathogen invasion. Inappropriate or uncontrolled activation of the complement system can cause diseases characterized by serious tissue injury. Three main pathways can activate the complement system: classical, lectin, and alternative. Omeros is focused on development of therapeutics to treat diseases associated with the lectin and/or alternative pathways of complement.

MASP-2 Program - Lectin Pathway Disorders

MASP-2, a novel pro-inflammatory protein target, is the effector enzyme of the lectin pathway and is required for the function of this pathway. Omeros is developing antibodies and small-molecule inhibitors of MASP-2 as potential therapeutics for diseases in which the lectin pathway has been shown to contribute to significant tissue injury and pathology. When not treated, these diseases are typically characterized by significant end-organ damage, such as kidney or central nervous system injury. Importantly, inhibition of MASP-2 has been demonstrated not to interfere with the antibody-dependent classical complement activation pathway, a critical component of the acquired immune response to infection. In addition to our clinical programs evaluating narsoplimab, we have generated positive preclinical data from MASP-2 inhibition in *in vivo* models of AMD, myocardial infarction, diabetic neuropathy, stroke, ischemia-reperfusion injury, and other diseases and disorders. We own or hold worldwide exclusive licenses to rights related to MASP-2, the antibodies targeting MASP-2 and the therapeutic applications for those antibodies.

Narsoplimab (OMS721)

The lead candidate in our MASP-2 inhibitor program is narsoplimab (OMS721), a proprietary, patented human monoclonal antibody targeting MASP-2. Narsoplimab is in clinical development for several indications.

Hematopoietic stem-cell transplant-associated thrombotic microangiopathy ("TA-TMA"): We successfully completed a pivotal clinical trial for narsoplimab in TA-TMA and previously submitted to the FDA a biologics license application ("BLA") seeking marketing approval for narsoplimab in this indication. In late 2021, FDA issued a complete response letter ("CRL") with respect to the BLA in which the agency indicated that additional information would be needed to support regulatory approval. We appealed FDA's decision to issue the CRL through a formal dispute resolution process that concluded in late 2022. Although our appeal was denied, the decision identified potential paths for resubmission of the BLA based on both response data and survival data from the completed pivotal trial versus a historical control group, with or without an independent literature analysis or based on survival data alone. Consistent with subsequent interactions with FDA's review division, we submitted to FDA in the fall of 2023 an analysis plan to assess already existing clinical trial data, existing data from a historical control population available from an external source, data from the narsoplimab expanded access program, and data directed to the mechanism of action of narsoplimab. We are having ongoing discussions with the agency regarding the proposed analysis plan. As a result, we are currently unable to estimate when we will submit the BLA or, subsequently, FDA's timing for a decision regarding approval. There can be no guarantee that FDA's specific recommendations for resubmission will be acceptable to Omeros in terms of the time and/or expenditure required or that any resubmission of the BLA will result in approval of narsoplimab for TA-TMA.

In the U.S., FDA has granted narsoplimab (1) breakthrough therapy designation in patients who have persistent TMA despite modification of immunosuppressive therapy, (2) orphan drug designation for the prevention (inhibition) of complement-mediated TMAs, and (3) orphan drug designation for the treatment of TA-TMA. The European Commission (the "EC") also granted narsoplimab designation as an orphan medicinal product for treatment in hematopoietic stem cell transplantation.

In Europe, the European Medicines Agency ("EMA") has confirmed narsoplimab's eligibility for the EMA's centralized review of a single marketing authorization application ("MAA") that, if approved, authorizes the product to be marketed in all EU member states and European Economic Area countries. We expect to complete our MAA submission following the resubmission of our BLA to FDA.

COVID-19 and Acute Respiratory Distress Syndrome ("ARDS"): There is strong and increasingly well-established evidence of the central role of the lectin pathway in COVID-19 and ARDS and we have developed both mechanistic and proof-of-concept clinical data indicating that narsoplimab may be an effective therapeutic for COVID-19, ARDS and/or related indications. We also continue to explore the mounting evidence that MASP-2 and the lectin pathway are important drivers of post-acute sequelae SARS-CoV-2 ("PASC"), commonly known as long COVID, as well as potential approaches to identify acute COVID-19 patients at high-risk for hospitalization and mortality, to identify those PASC patients with hyperactive lectin pathway-driven disease, and to monitor response to treatment with MASP-2 inhibitors.

Narsoplimab has been administered under compassionate use to treat COVID-19 patients in Italy and in the U.S., achieving encouraging results. Additionally, narsoplimab was the only complement inhibitor included in the I-SPY COVID-19 trial, a nationwide, late-stage adaptive platform trial sponsored by Quantum Leap Healthcare Collaborative ("Quantum Leap"), that evaluated multiple agents as potential treatments for severe COVID-19 requiring mechanical ventilation. Results of the I-SPY COVID-19 trial were reported in September 2022. The narsoplimab treatment arm was terminated prior to accrual of the maximum of 125 patients on the basis of analysis in a pre-consented patient population in which substantial bias was detected. Although narsoplimab was not observed in this study to shorten the time to recovery in critically ill patients with COVID-19, analysis in the randomized patient population showed that the addition of narsoplimab to treatment of critically ill patients with COVID-19 reduces the mortality risk (hazard ratio [HR]=0.81, with probability [HR <1] equal to 0.77). In approximately half of the patients who died in the narsoplimab group, narsoplimab was not given or was prematurely stopped, with those patients dying 9 to 35 days later. Neither the trial's futility nor graduation criteria had been met in the analysis of the randomized population at the time the narsoplimab arm was terminated. Narsoplimab demonstrated the greatest reported survival benefit of all therapeutics evaluated in the I-SPY platform trial.

We have also developed an assay platform to identify hyperactivation of the lectin pathway. Lectin pathway hyperactivation is correlated with COVID-19-related-ARDS and may be involved in the pathogenesis of other forms of ARDS and/or PASC. As such, the assay may be useful to identify patients who are at greatest risk of hospitalization and/or mortality as well as those who are particularly amenable to lectin pathway inhibition therapy for the treatment of one or more of these conditions. We continue to validate the clinical correlation of lectin pathway hyperactivation with COVID-19, ARDS and PASC. We continue to engage in discussions with potential partners as well as with representatives of the U.S. government regarding potential opportunities to obtain funding and advance development of our potential diagnostic and/or therapeutic product candidates for COVID-19, PASC or other infectious diseases.

IgA Nephropathy: In October 2023, we announced the results of a pre-specified interim analysis in ARTEMIS-IGAN, our Phase 3 clinical trial evaluating narsoplimab for the treatment of immunoglobulin A ("IgA") nephropathy. Topline results of the interim analysis showed that narsoplimab did not achieve statistical significance on the primary endpoint of reduction in proteinuria from baseline compared to placebo. Based on the absence of statistical significance and as previously agreed with FDA, we determined not to submit an application for approval of narsoplimab in this indication and the ARTEMIS-IGAN clinical trial has been discontinued.

OMS1029

Our lectin pathway program also includes OMS1029, our long-acting antibody targeting MASP-2. This next-generation MASP-2 inhibitor is intended to be complementary to narsoplimab, enabling us to pursue chronic indications in which dosing convenience would be of significant benefit to patients. Dosing of all cohorts in a single-ascending dose Phase 1 clinical trial of OMS1029 was successfully completed in early 2023. Pharmacokinetic ("PK") and pharmacodynamic ("PD") data show dose-proportional exposure and sustained lectin pathway inhibition, consistent with dosing of OMS1029 once quarterly, either intravenously or subcutaneously. Dosing has also been completed in both of two planned cohorts of our ongoing Phase 1 multiple-ascending-dose study of OMS1029 in healthy volunteers and we expect the study to conclude in mid-2024. OMS1029 has been well tolerated to date with no safety concerns identified. We continue to evaluate several potential indications for Phase 2 clinical development for OMS1029.

MASP-3 Program - Alternative Pathway Disorders

As part of our program to develop complement-targeted therapeutics, we have identified MASP-3, which has been shown to be the key activator of the complement system's alternative pathway ("APC"), and we believe that we are the first to make this and related discoveries associated with the APC. The complement system is part of the immune system's innate response, and the APC is considered the amplification loop within the complement system. MASP-3 is responsible for the conversion of pro-factor D to mature factor D; which is necessary for the activation of the APC.

We believe that MASP-3 inhibitors have the potential to treat patients suffering from a wide range of diseases and conditions including: PNH; C3G; multiple sclerosis; neuromyelitis optica; age-related macular degeneration; Alzheimer's disease; systemic lupus erythematosus; diabetic retinopathy; chronic obstructive pulmonary disease; antineutrophil cytoplasmic antibody-associated vasculitis; anti-phospholipid syndrome; atherosclerosis; myasthenia gravis and others. Several of these indications have been clinically validated by other agents targeting the APC. Our MASP-3 program has also generated positive data in a well-established animal model of arthritis.

OMS906

The lead candidate in our MASP-3 inhibitor program is OMS906, a proprietary, patented human monoclonal antibody targeting MASP-3. Clinical development of OMS906 is currently focused on rapidly advancing to Phase 3 clinical trials in multiple APC-related disorders, including PNH and C3G. OMS906 received designation from FDA as an orphan drug for the treatment of PNH in July 2022.

Paroxysmal nocturnal hemoglobinuria ("PNH"): We have three ongoing Phase 2 clinical trials evaluating OMS906 for PNH. One in PNH patients who have not previously been treated with a complement inhibitor, and the second in PNH patients who have had an unsatisfactory response to ravulizumab, an inhibitor of complement component 5 ("C5"). The third Phase 2 clinical trial is an open-label extension study to assess the long-term efficacy and safety of OMS906 in patients who have completed either of the other two PNH Phase 2 clinical trials.

In December 2023, updated results from a pre-specified interim analysis of our ongoing Phase 2 clinical trial of OMS906 in complement-inhibitor-naïve adults with PNH were featured in a podium presentation at the annual meeting of the American Society of Hematology. The interim analysis results showed statistically significant and clinically meaningful improvements in all measured markers of hemolysis, including hemoglobin and lactate dehydrogenase. No patients were reported to have had a clinical breakthrough of PNH or a thrombotic event, and none were reported to require a transfusion while receiving OMS906 treatment.

Enrollment is complete and dosing is ongoing in our Phase 2 trial evaluating OMS906 in PNH patients who have had an unsatisfactory response to the C5 inhibitor ravulizumab. Utilizing a "switch-over" design, this study enrolls PNH patients receiving ravulizumab, adds OMS906 to provide combination therapy with ravulizumab for 24 weeks, and then, in those patients who demonstrate a hemoglobin response with the combination therapy, switches to OMS906 monotherapy. Data from a pre-specified interim analysis showed that the addition of OMS906 therapy to ravulizumab treatment resulted in statistically significant and clinical meaningful improvements in both mean hemoglobin levels and absolute reticulocyte counts by week 4 of combination therapy, with a sustained response demonstrated through week 24 (the latest assessment prior to the interim analysis cutoff). Full details from the interim analysis are expected to be presented at a major hematology conference in mid-2024. Interim analysis data from the monotherapy portion of the trial is expected to be available in late 2024.

We have initiated an open-label extension study to assess the long-term efficacy and safety of OMS906 in patients with PNH. In the extension study, PNH patients who have completed a previous study evaluating OMS906 roll directly into the extension study without a break in OMS906 treatment. Data from this study will contribute to a planned BLA for OMS906 in the treatment of PNH. Based on PK data from a successful Phase 1 single-ascending-dose study of OMS906 in healthy subjects and interim data from our ongoing clinical trials in PNH patients, we are exploring two different dosing frequencies - once every eight weeks and once every 12 weeks - for the Phase 3 studies and commercialization.

In February 2024 we met with FDA to discuss our development program for OMS906 in PNH. We presented clinical and nonclinical data and requested input on expectations for Phase 3 studies and BLA submission. FDA confirmed that the scope of our nonclinical program is sufficient to support Phase 3 clinical studies and provided input on dosing and design of the proposed Phase 3 program to support a BLA in PNH. We expect to meet again with FDA later this year to discuss further details of the design of our Phase 3 studies. Phase 3 clinical trials evaluating OMS906 in PNH are targeted to begin in late 2024.

Complement 3 glomerulopathy ("C3G"): We also have an ongoing Phase 2 clinical program evaluating OMS906 for the treatment of C3G, a rare and debilitating renal disease driven by complement dysregulation. Notably, the relevance of the alternative pathway to C3G has been clinically validated in a Phase 3 trial with another inhibitor of the alternative pathway that reported positive results in the treatment of C3G. Although a protocol amendment to modify the OMS906 dose based on information learned from our PNH program delayed initiation of the study, sites are now open in multiple countries and patients are being screened for enrollment. We are targeting to initiate Phase 3 development for C3G in the first part of 2025, after Phase 2 results are available and discussions occur with regulators.

Preclinical Complement Inhibitor Programs

We have also directed efforts to development of small-molecule inhibitors of MASP-2 and MASP-3 designed for oral administration. In our MASP-2 small molecule inhibitor program we continue to advance testing to enable the filing of an investigational new drug application. Our MASP-3 small-molecule inhibitor is advancing rapidly toward selection of a drug development candidate.

Other Clinical Programs

PDE7 Inhibitor Programs - OMS527

Our PDE7 inhibitor programs, which we refer to as OMS527, comprise multiple PDE7 inhibitor compounds and are based on our discoveries of previously unknown links between PDE7 and any addiction or compulsive disorder, and between PDE7 and any movement disorders. PDE7 appears to modulate the dopaminergic system, which plays a significant role in regulating both addiction and movement. We believe that PDE7 inhibitors could be effective therapeutics for the treatment of addictions and compulsions as well as for movement disorders. Data generated in preclinical studies support the use of PDE7 inhibitors in both of these therapeutic areas.

Cocaine Use Disorder ("CUD"): In April 2023, we were awarded a grant from the National Institute on Drug Abuse, part of the National Institutes of Health, to develop our lead orally administered PDE7 inhibitor compound, for which we have successfully completed a Phase 1 study, for the treatment of CUD. The grant amount, a total of $6.69 million over three years, is intended to support preclinical cocaine interaction/toxicology studies to assess safety of the therapeutic candidate in the presence of concomitant cocaine administration, as well as an in-patient, placebo-controlled clinical study evaluating the safety and effectiveness of OMS527 in adults with CUD who receive concurrent intravenous cocaine. The preclinical study is intended to provide the toxicology data necessary to support the human study of OMS527 in CUD. That study is underway and is expected to be completed in late 2024.

Levodopa-induced dyskinesia ("LID"): With investigators at Emory University, we are also evaluating OMS527 as a potential treatment for LID, which are involuntary and often crippling movements in patients with Parkinson's disease that are caused by prolonged treatment with levodopa, the most prescribed therapy for Parkinson's disease. More than 10 million patients are living with Parkinson's disease worldwide. Reportedly 50 percent or more of levodopa-treated patients with Parkinson's disease suffer from LID.

We hold an exclusive license to certain PDE7 inhibitors claimed in patents and pending patent applications owned by Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo"), as successor-in-interest to Asubio Pharma Co., Ltd. for use in the treatment of movement, addiction and compulsive disorders as well as other specified indications. For a more detailed description of our agreement with Daiichi Sankyo, see "License and Development Agreements" below.

PPARγ Program - OMS405

In our peroxisome proliferator-activated receptor gamma ("PPARγ") program, we have engaged in development of proprietary compositions that include PPARγ agonists for the treatment and prevention of addiction to substances of abuse, which may include opioids, nicotine and alcohol. We believe that Omeros is the first to demonstrate a link between PPARγ and addiction disorders. Data from clinical studies and from animal models of addiction suggest that PPARγ agonists could be efficacious in the treatment of a wide range of addictions.

Our collaborators at The New York State Psychiatric Institute have completed two Phase 2 clinical trials related to our PPARγ program. These studies evaluated a PPARγ agonist, alone or in combination with other agents, for treatment of addiction to heroin and to nicotine. The published results of the heroin study demonstrated that, although not altering the reinforcing or positive subjective effects of heroin, the PPARγ agonist significantly reduced heroin craving and overall anxiety. The National Institute on Drug Abuse ("NIDA") provided substantially all of the funding for these clinical trials and solely oversaw the conduct of these trials. We have the right or expect to be able to reference the data obtained from these studies for any future FDA submission and continue to retain all other rights in connection with the PPARγ program.

We have also reported positive results (*i.e.*, decreased cravings and protection of brain white matter) from a Phase 2 clinical trial conducted by an independent investigator evaluating the effects of a PPARγ agonist in patients with cocaine use disorder. An investigator-sponsored study evaluating the effects of a PPARγ agonist on the prevention of relapse following treatment of cocaine use disorder is ongoing. The study is funded by NIDA.

We own patents, patent applications and other intellectual property rights related to our PPARγ program, as described under "Intellectual Property" below.

Preclinical Programs and Platforms

Immuno-Oncology Platform

We have five immuno-oncology (I-O) platforms in preclinical development – adoptive T-cell therapy, CART-T, signaling-driven immunomodulators, antigen-driven immunomodulators that function both as therapeutics and vaccines, and oncotoxins. To date, *in vitro, ex vivo* and animal studies using human cellular components have been positive with high response rates. These data collectively reinforce the scientific basis for each platform, confirming our rationale for their design and development. The data from our studies to date have demonstrated a number of potential advantages of our immuno-oncology franchise over other I-O approaches.

Our I-O franchise should be applicable to cancers broadly. Rather than targeting only cell-surface antigens, our I-O franchise is designed to target both cell-surface and intracellular cancer targets, significantly broadening the range of indications. Unlike other therapeutic approaches that affect either CD4 or CD8 levels, we have designed and demonstrated the ability of our technologies to increase levels of both CD4 and CD8 cells against a given cancer, both of which are necessary to kill tumor cells. By increasing both the CD4 and CD8 cells, we should also be able to mitigate the "treatment exhaustion" – or the wearing-off of the treatment effect – seen with many currently available therapies. This would allow repeated treatment, providing a sustained and better anti-tumor response.

Our cellular platforms do not require modification or engineering. Instead, cells from the patient are simply treated outside the body and administered back to the patient. We expect this simplicity in process, if achieved, to represent a major advance over currently available T-cell therapies, greatly decreasing both preparation time and cost. When injected into the body, our novel biologic molecules should result not only in elimination of tumor cells but, importantly, in immune memory against future cancer relapse. Our core technology is also amenable potentially to cancer prevention broadly.

We believe that all five platforms are entirely novel and proprietary. We continue to confirm our results and to generate new data, all of which contribute to our intellectual property position.

Sales and Marketing

We have retained all worldwide marketing and distribution rights to our drug candidates and our development programs. As such, we will be able to market any drug candidate that is approved in the future independently, through arrangements with third parties, or via some combination of these approaches.

We maintained internal marketing and sales capabilities with respect to OMIDRIA until the completion of the divestiture of that product on December 23, 2021. As part of the divestiture, substantially all of our OMIDRIA sales and marketing team members accepted employment with Rayner and were separated from their employment at Omeros, effective as of December 31, 2021.

Manufacturing, Supply and Commercial Operations

We currently do not own or operate manufacturing facilities. We utilized contract manufacturers to produce, store and distribute OMIDRIA and currently rely on third parties to produce sufficient quantities of our drug candidates for use in pre-clinical and clinical studies and for the manufacture of narsoplimab for commercial use following potential regulatory approval.

OMIDRIA. We assigned or otherwise transitioned to Rayner our agreements with the third parties that produced, stored and distributed OMIDRIA. We required manufacturers that produced active pharmaceutical ingredients ("APIs") and finished drug products to operate in accordance with current Good Manufacturing Practices ("cGMPs") and all other applicable laws and regulations.

In the U.S., we sold OMIDRIA through a limited number of wholesalers that distributed the product to ASCs and hospitals. Title transferred upon delivery of OMIDRIA to the wholesaler. For additional information, see Part II, Item 8, "Note 7 – Discontinued Operations – Sale of OMIDRIA" to our Consolidated Financial Statements in this Annual Report on Form 10-K.

Drug Candidates. We have laboratories in-house for analytical method development, bioanalytical testing, formulation, stability testing and small-scale compounding of laboratory supplies of drug candidates. We utilize contract manufacturers to produce sufficient quantities of drug candidates for use in preclinical and clinical studies and to store and distribute our drug candidates. We require manufacturers that produce bulk drug substance and finished drug products for clinical use to operate in accordance with cGMPs and all other applicable laws and regulations. We anticipate that we will rely on contract manufacturers to develop and manufacture our drug candidates for commercial sale. We maintain agreements with potential and existing manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to our drug candidates.

In July 2019, we entered into a master services agreement with Lonza Biologics Tuas Pte. Ltd. ("Lonza") for the commercial production of narsoplimab and for certain regulatory support and related services to be provided by Lonza from time to time. Under the agreement Lonza will manufacture narsoplimab pursuant to purchase orders issued in accordance with certain forecast and confirmation procedures specified in the contract. We will purchase narsoplimab that meets agreed specifications in batches, with the price per batch varying according to the total number of batches ordered for serial production in a single manufacturing campaign. We are obligated to purchase a minimum number of batches annually beginning on a specified anniversary of the first commercial sale of narsoplimab in either the U.S. or EU. We may be obligated to pay certain fees to Lonza upon cancellation of purchase orders.

The initial term of the agreement expires five years after the first commercial sale of narsoplimab in either the U.S. or EU and is subject to automatic renewal for an additional four-year term unless we provide notice of non-renewal at least three years prior to the end of the initial term. In addition, either party may terminate the agreement, subject to applicable notice and cure periods under certain circumstances. Other than our agreement for commercial supply of narsoplimab, we have not yet entered into a commercial supply agreement for any of our drug candidates.

If approved for commercial sale in the U.S., we expect to utilize one or more wholesalers for distribution of narsoplimab.

License and Development Agreements

MASP-3. In August 2020, we entered into a technology license agreement with Xencor, Inc., pursuant to which we received an exclusive license to apply Xencor's Xtend Fc technology to OMS906 and options to access exclusive licenses to apply Xtend Fc technology to additional antibodies (the "Xencor Agreement"). Exercise of an option to access additional licenses would require payment of a $3.0 million upfront license fee. With respect to each antibody for which we license the Xencor technology we are obligated to make milestone payments of up to $65.0 million, comprised of $15.0 million in development milestones, $25.0 million in regulatory milestones and $25.0 million in sales milestones. In August 2023, we paid $5.0 million to Xencor in connection with the achievement of a development milestone in our OMS906 program. We are obligated on a product-by-product and country-by-country basis to pay Xencor royalties in the mid-single digit percentage range on net sales of any product covered by the license so long as there is a valid, subsisting and enforceable claim in any patents or patent applications covering the licensed technology. Thereafter, the royalty rate is reduced to the low single-digit percentage range, if the applicable licensed product is covered by Xencor know-how, or to zero, if the applicable licensed product is not covered by Xencor know-how. The term of the Xencor Agreement continues on a product-by-product basis until the later of (i) expiration for the last-to-expire patent covering the licensed technology or (ii) five years from the date of first commercial sale of the applicable product.

PDE7. Under an agreement with Daiichi Sankyo, we hold an exclusive worldwide license to PDE7 inhibitors claimed in certain patents and pending patent applications owned by Daiichi Sankyo for use in the treatment of (1) movement disorders and other specified indications, (2) addiction and compulsive disorders and (3) all other diseases except those related to dermatologic conditions. Under the agreement, we agreed to make milestone payments to Daiichi Sankyo of up to an aggregate total of $33.5 million upon the achievement of certain events in each of these three fields; however, if only one of the three indications is advanced through the milestones, the total milestone payments would be $23.5 million. The milestone payment events include successful completion of preclinical toxicology studies; dosing of human subjects in Phase 1, 2 and 3 clinical trials; receipt of marketing approval of a PDE7 inhibitor drug candidate; and reaching specified sales milestones. In addition, Daiichi Sankyo is entitled to receive from us a low single-digit percentage royalty of any net sales of a PDE7 inhibitor licensed under the agreement by us and/or our sublicensee(s) provided that, if the sales are made by a sublicensee, then the amount payable by us to Daiichi Sankyo is capped at an amount equal to a low double-digit percentage of all royalty and specified milestone payments received by us from the sublicensee.

The term of the agreement with Daiichi Sankyo continues so long as there is a valid, subsisting and enforceable claim in any patents covered by the agreement. The agreement may be terminated sooner by us, with or without cause, upon 90 days advance written notice or by either party following a material breach of the agreement by the other party that has not been cured within 90 days or immediately if the other party is insolvent or bankrupt. Daiichi Sankyo also has the right to terminate the agreement if we and our sublicensee(s) cease to conduct all research, development and/or commercialization activities for a PDE7 inhibitor covered by the agreement for a period of six consecutive months, in which case all rights held by us under Daiichi Sankyo's patents will revert to Daiichi Sankyo.

Competition

Overview. The pharmaceutical and biotechnology industry is highly competitive and characterized by a number of established, large pharmaceutical and biotechnology companies as well as smaller companies like ours. We expect to compete with other pharmaceutical and biotechnology companies, and our competitors may:

- develop and market products that are less expensive, more effective or safer than our future products;
- commercialize competing products before we can launch our products;
- operate larger research and development programs, possess greater manufacturing capabilities or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to remain current with the rapid changes in each technology. Further, our competitors may render our technologies obsolete by advancing their existing technological approaches or developing new or different approaches. If we fail to stay at the forefront of technological change, we may be unable to compete effectively.

Drug Candidates, Development Programs and Platforms. There are a number of complement-targeted therapeutics that are in advanced stages of clinical development, or which have been approved for commercial use. These include Soliris® (eculizumab), Ultomiris® (ravulizumab-cwvz), Empaveli® (pegcetacoplan), Tavneos® (avocopan) and Fabhalta® (iptacopan). Narsoplimab, OMS1029 and/or OMS906 will face competition from one or more of these products if approved for any indication(s) for which one or more of these potentially competitive products are also approved or for which a potentially competitive product is used off-label to treat a relevant condition.

Intellectual Property

We have retained control of all worldwide manufacturing, marketing and distribution rights for each of our drug candidates and programs. Some of our drug candidates and programs are based on inventions and other intellectual property rights that we acquired through assignments, exclusive licenses or acquisitions described in further detail under "License and Development Agreements" above.

As of February 15, 2024, we owned or held worldwide exclusive licenses to a total of 78 issued patents and 60 pending patent applications in the U.S. and 1,334 issued patents and 580 pending patent applications in foreign markets directed to therapeutic compositions and methods and other technologies related to our research and development programs. For each program, our decision to seek patent protection in specific foreign markets, in addition to the U.S., is based on many factors, including one or more of the following: our available resources, the size of the commercial market, the presence of a potential competitor or a contract manufacturer in the market and whether the legal authorities in the market effectively enforce patent rights.

- *MASP-2 Program - Narsoplimab (OMS721) and OMS1029.* We own and hold worldwide exclusive licenses to rights in connection with MASP-2, antibodies targeting MASP-2, small-molecule MASP-2 inhibitors, and related therapeutic applications. As of February 15, 2024, we exclusively controlled 38 issued patents and 32 pending patent applications in the U.S., and 793 issued patents and 435 pending patent applications in foreign markets, related to our MASP-2 program, including narsoplimab and our second-generation MASP-2 antibody OMS1029. Our MASP-2-related patents have terms that will expire as late as 2038 and, if currently pending patent applications are issued, as late as 2043.

- *MASP-3 Program - OMS906*. We own and exclusively control rights in connection with MASP-3, antibodies targeting MASP-3 and related therapeutic applications. We also hold an exclusive license from Xencor, Inc. for the application of certain antibody technology to OMS906, as well as the option to obtain additional licenses to such technology for exclusive application to additional antibodies that we may select. As of February 15, 2024, we exclusively controlled four issued patents and eight pending patent applications in the U.S. and 188 issued and 104 pending patent applications in foreign markets that are related to our MASP-3 program. Our MASP-3-related patents have terms that will expire as late as 2037 and, if currently pending patent applications are issued, as late as 2043.

- *PPARγ Program - OMS405*. As of February 15, 2024, we owned three issued patents and one pending patent application in the U.S., and 37 issued patents and two pending patent applications in foreign markets, directed to our discoveries linking PPARγ and addictive disorders. Our PPARγ-related patents have terms that will expire as late as 2030.

- *PDE7 Program - OMS527*. As of February 15, 2024, we owned two issued patents and two pending patent application in the U.S., and 61 issued patents and two pending patent applications in foreign markets directed to our discoveries linking PDE7 to movement disorders, as well as three issued patent and two pending patent applications in the U.S., and 54 issued patents and three pending patent applications in foreign markets directed to the link between PDE7 and addiction and compulsive disorders. Additionally, under a license from Daiichi Sankyo, we exclusively control rights to two issued U.S. patents and 53 issued patents in foreign markets that are directed to proprietary PDE7 inhibitors. Our PDE7-related patents have terms that will expire as late as 2031 and, if currently pending patent applications are issued, as late as 2043. For a more detailed description of our agreement with Daiichi Sankyo, see "License and Development Agreements" below.

- *Immuno-oncology Program.* Our Immuno-oncology program includes five proprietary platforms relating to potential therapies for cancer. As of February 15, 2024, we owned two pending patent applications in foreign markets directed to potential cancer therapies.

All of our employees enter into our standard employee proprietary information and inventions agreement, which includes confidentiality provisions and provides us ownership of all inventions and other intellectual property made by our employees that pertain to our business or that relate to our employees' work for us or that result from the use of our resources. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of the use, formulation and structure of our drug candidates and the methods used to manufacture them, as well as on our ability to defend successfully these patents against third-party challenges. Our ability to protect our drug candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S., and tests used for determining the patentability of patent claims in all technologies are in flux. The pharmaceutical, biotechnology and other life sciences patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents that we own or have licensed or in third-party patents.

We have registered, and intend to maintain, the trademark "OMEROS" within the U.S. Patent and Trademark Office in connection with the products and services we offer. We are not aware of any material claims of infringement or other challenges to our right to use the "OMEROS" trademark in the U.S.

Government Regulation

Government authorities in the U.S., the EU and other countries extensively regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing, and export and import of drug and biologic products including the drug candidates that we are developing. Failure to comply with applicable requirements, both before and after receipt of regulatory approval, may subject us, our third-party manufacturers, and other partners to administrative and judicial sanctions, such as warning letters, product recalls, product seizures, a delay in approving or refusal to approve pending applications, civil and other monetary penalties, total or partial suspension of production or distribution, injunctions, and/or criminal prosecutions.

In the U.S., our drug candidates are regulated by FDA as drugs or biologics under the Federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations and under the Public Health Service Act ("PHSA"). In the EU, our drug candidates are regulated by the EMA and national medicines regulators under the rules governing medicinal products in the EU as well as national regulations in individual countries. Our drug candidates are in various stages of testing and none of our drug candidates has received marketing approval from FDA or the applicable regulatory authorities in the EU.

The steps required before a product may be approved for marketing by FDA, or the applicable regulatory authorities outside of the U.S., typically include the following:

- formulation development and manufacturing process development;
- preclinical laboratory and animal testing;
- submission to FDA of an Investigational New Drug application ("IND") for human clinical testing, which must become effective before human clinical trials may begin; and in countries outside the U.S., a Clinical Trial Application ("CTA"), is filed according to the country's local regulations;
- adequate and well-controlled human clinical trials to establish the efficacy and safety of the product for each indication for which approval is sought;
- adequate assessment of drug product stability to determine shelf life/expiry dating;
- in the U.S., submission to FDA of a New Drug Application ("NDA"), in the case of a drug product, or a BLA in the case of a biologic product and, in Europe, submission to the EMA or a national regulatory authority of an MAA;
- satisfactory completion of inspections of one or more clinical sites at which clinical trials with the product were carried out and of the manufacturing facility or facilities at which the product is produced to assess compliance with Good Clinical Practices ("GCPs"), and cGMPs; and
- FDA review and approval of an NDA or BLA, or review and approval of an MAA by the applicable regulatory authorities in the EU.

Manufacturing. Manufacturing of drug products for use in clinical trials must be conducted according to relevant national and international guidelines, for example, cGMP. Process and formulation development are undertaken to design suitable routes to manufacture the drug substance and the drug product for administration to animals or humans. Analytical development is undertaken to obtain methods to quantify the potency, purity and stability of the drug substance and drug product as well as to measure the amount of the drug substance and its metabolites in biological fluids, such as blood.

Preclinical Tests. Preclinical tests include laboratory evaluations and animal studies to assess efficacy, toxicity and pharmacokinetics. The results of the preclinical tests, together with manufacturing information, analytical data, clinical development plan, and other available information are submitted as part of an IND or CTA.

The IND/CTA Process. An IND or CTA must become effective before human clinical trials may begin. INDs are extensive submissions including, among other things, the results of the preclinical tests, together with manufacturing information and analytical data. In addition to including the results of the preclinical studies, the IND will also include one or more protocols for proposed clinical trials detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. An IND will become effective 30 days after receipt by FDA unless, before that time, FDA raises concerns or questions and imposes a clinical hold. In that event, the IND sponsor and FDA must resolve any outstanding FDA concerns or questions before the clinical hold is lifted and clinical trials can proceed. Similarly, a CTA must be cleared by the local independent ethics committee and competent authority prior to conducting a clinical trial in the country in which it was submitted. There can be no assurance that submission of an IND or CTA will result in authorization to commence clinical trials. Once an IND or CTA is in effect, there are certain reporting requirements.

Clinical Trials. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified personnel and must be conducted in accordance with local regulations and GCPs. Clinical trials are conducted under protocols detailing, for example, the parameters to be used in monitoring patient safety and the efficacy criteria, or endpoints, to be evaluated. Each trial must be reviewed and approved by an independent institutional review board or ethics committee for each clinical site at which the trial will be conducted before it can begin. Clinical trials are typically conducted in three defined phases, but the phases may overlap or be combined:

- Phase 1 usually involves the initial administration of the investigational product to human subjects, who may or may not have the disease or condition for which the product is being developed, to evaluate the safety, dosage tolerance, pharmacodynamics and, if possible, to gain an early indication of the effectiveness of the product.

- Phase 2 usually involves trials in a limited patient population with the disease or condition for which the product is being developed to evaluate appropriate dosage, to identify possible adverse side effects and safety risks, and to evaluate preliminarily the effectiveness of the product for specific indications.

- Phase 3 clinical trials usually further evaluate and confirm effectiveness and test further for safety by administering the product in its final form in an expanded patient population.

We, our product development partners, institutional review boards or ethics committees, FDA or other regulatory authorities may suspend or terminate clinical trials at any time on various grounds, including a belief that the subjects are being exposed to an unacceptable health risk.

Disclosure of Clinical Trial Information. Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Information related to the product, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed for up to two years if the sponsor certifies that it is seeking approval of an unapproved product or that it will file an application for approval of a new indication for an approved product within one year. Clinical trials conducted in European countries are required to be registered at a similar public database maintained and overseen by European health authorities. Competitors may use this publicly available information to gain knowledge regarding the design and progress of our development programs.

The Application Process. If the necessary clinical trials are successfully completed, the results of the preclinical trials and the clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to FDA in the form of an NDA or a BLA, as applicable, and to the EMA or national regulators in the form of an MAA, requesting approval to market the product for a specified indication. In the EU, an MAA may be submitted to the EMA for review and, if the EMA gives a positive opinion, the EC may grant a marketing authorization that is valid across the EU (centralized procedure). Alternatively, an MAA may be submitted to one or more national regulators in the EU according to one of several national or decentralized procedures. The type of submission in Europe depends on various factors and must be cleared by the appropriate authority prior to submission. For most of our drug candidates, the centralized procedure will be either mandatory or available as an option.

If the regulatory authority determines that the application is not acceptable, it may refuse to accept the application for filing and review, outlining the deficiencies in the application and specifying additional information needed to file the application. Notwithstanding the submission of any requested additional testing or information, the regulatory authority ultimately may decide that the proposed product is not safe or effective, or that the application does not otherwise satisfy the criteria for approval. In the U.S., to support an approval an NDA must demonstrate, among other things, that the proposed drug product is safe and effective, has a favorable benefit-risk profile, is manufactured in a way that preserves its identity, strength, purity and potency, and that its labeling is adequate and not false or misleading. A similar standard exists for BLAs. Before approving an NDA or BLA, or an MAA, FDA or the EMA, respectively, may inspect one or more of the clinical sites at which the clinical studies were conducted to ensure that GCPs were followed and may inspect facilities at which the product is manufactured to ensure satisfactory compliance with cGMP. The FDA may refer the NDA or BLA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendation. In addition, even if a drug candidate satisfied its endpoints with statistical significance during clinical trials, FDA could determine that the overall balance of risks and benefits for the drug candidate is not adequate to support approval, or only justifies approval for a narrow set of clinical uses and/or subject to restricted distribution or other burdensome post-approval requirements or limitations. If approval is obtained changes to the approved product such as adding new indications, manufacturing changes, or additional labeling claims will require submission of a supplemental application, referred to as a variation in the EU, or, in some instances, a new application, for further review and approval. The testing and approval process requires substantial time, effort, and financial resources, and we cannot be sure that any future approval will be granted on a timely basis, if at all.

Some of our drug candidates, such as those from our MASP-2 and MASP-3 programs, are considered biologics because they are derived from natural sources as opposed to being chemically synthesized. The added complexity associated with manufacturing biologics may result in additional monitoring of the manufacturing process and product changes.

In addition, we, our suppliers and our contract manufacturers are required to comply with extensive regulatory requirements both before and after approval. For example, we must establish a pharmacovigilance system and are required to report adverse reactions and production problems, if any, to the regulatory authorities. If any of our drug candidates are approved, we will be required to also comply with certain requirements concerning advertising and promotion for our products. The regulatory authorities may impose specific obligations as a condition of the marketing authorization, such as additional safety monitoring, or the conduct of additional clinical trials or post-marketing safety studies, or the imposition of a Risk Evaluation and Mitigation Strategy ("REMS"), which could include significant restrictions on distribution or use of the product. Also, quality control and manufacturing procedures must continue to conform to cGMPs after approval. Accordingly, manufacturers must continue to expend time, money, and effort in all areas of regulatory compliance, including production and quality control to comply with cGMPs. In addition, discovery of problems such as safety issues may result in changes in labeling or restrictions on a product manufacturer or marketing authorization holder, including removal of the product from the market.

Fast-Track and Priority Review Designations. Section 506(b) of the FDCA provides for the designation of a drug as a fast-track product if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. A program with fast-track status is afforded greater access to FDA for the purpose of expediting the product's development, review and potential approval. Many products that receive fast-track designation are also considered appropriate to receive priority review, and their respective applications may be accepted by FDA as a rolling submission in which portions of an NDA or BLA are reviewed before the complete application is submitted. Together, these may reduce time of development and FDA review time. In Europe, products that are considered to be of major public health interest are eligible for accelerated assessment, which shortens the review period. The grant of fast-track status, priority review or accelerated assessment does not alter the standard regulatory requirements for obtaining marketing approval.

Breakthrough Therapy Designation. In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act. This law established a regulatory process allowing for increased interactions with FDA with the goal of expediting development and review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Accelerated Approval. The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides a meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. In both cases, FDA must take into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Studies that are conducted to demonstrate a drug's effect on a surrogate or intermediate clinical endpoint for accelerated approval must be adequate and well-controlled as required by the FDCA.

Following accelerated approval, FDA requires that the company provide confirmatory evidence, which may include certain adequate and well-controlled post-marketing clinical studies to verify the clinical benefit of the product, and FDA may impose restrictions on distribution to assure safe use. Pursuant to new statutory authority under the Food and Drug Omnibus Reform Act of 2022, FDA can require confirmatory studies to be underway at the time of the accelerated approval. If the required confirmatory studies fail to verify the clinical benefit of the drug, or if the applicant fails to perform the required confirmatory studies with due diligence, FDA may withdraw approval of the drug under streamlined procedures in accordance with FDA's regulations. FDA may also withdraw approval of a drug if, among other things, other evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use.

The EU also has accelerated approval programs. In the EU, a marketing authorization may be granted on the basis of less complete data than are normally required in certain "exceptional circumstances," such as when the product's indication is encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive data. Alternatively, a conditional marketing authorization may be granted prior to obtaining the comprehensive clinical data required for a full MAA if a product fulfills an unmet medical need and the benefit to public health of the product's immediate availability outweighs the risk inherent in the incomplete data.

Orphan Drug Designation. Under the Orphan Drug Act ("ODA"), FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S. or more than 200,000 individuals in the U.S. for which the cost of developing and making the product available in the U.S. for this type of disease or condition is not likely to be recovered from U.S. sales for that product. The granting of orphan designation does not alter the standard regulatory requirements (other than payment of certain fees and the applicability of certain pediatric assessment requirements), nor does it alter the standards or process for obtaining marketing approval. The sponsor of a product that has an orphan drug designation qualifies for various development incentives specified in the ODA, including a tax credit of up to 25% of expenditures on qualified clinical testing for the orphan drug. Furthermore, if the orphan designated product subsequently receives the first FDA approval for the orphan indication, the product is entitled to an orphan drug exclusivity period, which means that FDA may not grant approval to any other application to market the same drug for the same indication for a period of seven years except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity for the protected indication. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. The EU has a similar Orphan Drug program to that of the U.S., and it is administered through the EMA's Committee for Orphan Medicinal Products.

Pediatric Testing and Exclusivity. In the U.S., NDAs and BLAs are subject to both mandatory pediatric testing requirements and voluntary pediatric testing incentives in the form of exclusivity. An additional six months of exclusivity in the U.S. may be granted to a sponsor of an NDA or BLA if the sponsor conducts certain pediatric studies, which studies are conducted pursuant to a written request from FDA. This process is initiated when FDA issues a Written Request for pediatric studies to determine if the drug or biologic could have meaningful pediatric health benefits. If FDA determines that the sponsor has conducted the requested pediatric studies in accordance with the written request, then an additional six months of exclusivity may attach in the case of a drug to any other regulatory exclusivity or patent protection applicable to the drug and, in the case of a biologic, to any other regulatory exclusivity applicable to the biologic. The EU has a similar requirement and incentive for the conduct of pediatric studies according to the pediatric investigation plan, which must be adopted by the EMA before an MAA may be submitted.

Expanded Access. "Expanded access" refers to the use of an investigational drug where the primary purpose is to diagnose, monitor, or treat a patient's disease or condition rather than to collect information about the safety or effectiveness of a drug. There are three FDA-recognized categories of expanded access trials: expanded access for individual patients, including for emergency use; expanded access for intermediate-size patient populations; and expanded access for large patient populations under a treatment IND or treatment protocol. For all types of expanded access, FDA must determine prior to authorizing expanded access that: (1) the patient or patients to be treated have a serious or life-threatening disease or condition and there is no comparable or satisfactory alternative therapy; (2) the potential patient benefit justifies the potential risks of use and that the potential risks are not unreasonable in the context of the disease or condition to be treated; and (3) granting the expanded access will not interfere with the initiation, conduct, or completion of clinical studies in support of the drug's approval. Only a licensed physician or the drug's manufacturer may apply for expanded access. Manufacturers are not required to supply the investigational product for expanded access. The FDA has established streamlined processes for physicians to request individual patient expanded access whereby physicians can submit a single patient IND. In cases of individual patient emergency expanded access, physicians can receive FDA approval for access by phone and follow up with the abbreviated form. In addition, the sponsor of an expanded access IND must submit IND safety reports and, in the cases of protocols continuing for one year or longer, annual reports to FDA.

U.S. Labeling, Marketing and Promotion. The FDA closely regulates the labeling, marketing and promotion of drugs. In general, our labeling and promotion must not be false or misleading in any particular, and claims that we make must be adequately substantiated. In addition, our approved labeling must include adequate directions to physicians for each intended use of our products. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties.

In addition to regulation by FDA, the research, manufacturing, distribution, sale and promotion of drug products in the U.S. are subject to regulation by various federal, state and local authorities, including CMS, other divisions of the U.S. Department of Health and Human Services (*e.g.*, the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. Violations of these laws are punishable by prison sentences, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information or impose other special requirements for the sale and marketing of drug products. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, federal and state "transparency laws" require manufacturers to track and report certain payments made to health care providers and, under some state laws, other information concerning our products. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Drug Supply Chain Security Act. Title II (the Drug Supply Chain Security Act (the "DSCSA")), of the Drug Quality and Security Act imposes on manufacturers of certain pharmaceutical products new obligations related to product tracking and tracing, among others, which began a several-year phase-in process in 2015. Among the requirements of this legislation, manufacturers subject to the DSCSA are required to provide certain documentation regarding the drug product to trading partners to which product ownership is transferred, label drug product with a product identifier (*i.e.*, serialize), respond to verification requests from trading partners, provide transaction documentation upon request by federal or state government entities, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers must be done electronically. For products and transactions falling within DSCSA's scope, manufacturers are required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, under the DSCSA, covered manufacturers have drug product investigation, quarantine, disposition, and notification responsibilities for product that is reasonably believed or that credible evidence shows to be counterfeit, diverted, stolen, intentionally adulterated such that the product would result in serious adverse health consequences or death, the subject of fraudulent transactions or otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Anti-counterfeiting and serialization requirements similar to those under the DSCSA have also been adopted in the EU and became effective in February 2019.

Foreign Regulatory Requirements. Outside of the U.S., our ability to conduct clinical trials or market our products will also depend on receiving the requisite authorizations from the appropriate regulatory authorities. The foreign regulatory approval processes include similar requirements and many of the risks associated with FDA and/or the EU approval process described above, although the precise requirements may vary from country to country.

Hatch-Waxman Act. In seeking approval for a drug through an NDA, applicants are required to list with FDA each patent with claims that cover the applicant's drug or an approved method of use of the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an Abbreviated New Drug Application ("ANDA") or a 505(b)(2) application. In this case the original NDA, i.e., the pioneer drug, is known as the "listed" drug or "reference-listed" drug. An ANDA provides for marketing of a drug that has the same active ingredients and, in some cases, also the same inactive ingredients, in the same strengths, route of administration and dosage form as the listed drug and has been shown through testing to be bioequivalent to the listed drug or receives a waiver from bioequivalence testing. ANDA applicants are generally not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug, other than the requirement for bioequivalence testing. Drugs approved in this way are considered therapeutically equivalent, and are commonly referred to as "generic equivalents" to the listed drug. These drugs then generally can be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA or 505(b)(2) applicant is required to certify to FDA concerning any patents listed for the referenced approved drug in FDA's Orange Book. Specifically, for each listed patent, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new drug. A certification that the new drug will not infringe the already approved drug's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the ANDA or 505(b)(2) applicant does not include a Paragraph IV certification, the ANDA or 505(b)(2) application will not be approved until all of the listed patents claiming the referenced drug have expired, except for any listed patents that only apply to uses of the drug not being sought by the ANDA or 505(b)(2) applicant.

If the ANDA or 505(b)(2) applicant has made a Paragraph IV certification, the applicant must also send a Paragraph IV Notice Letter to the NDA and patent holders once the ANDA or 505(b)(2) application has been accepted for filing by FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the Paragraph IV Notice Letter. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV Notice Letter automatically prevents FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, modification by a court or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the reference-listed drug has expired. The U.S. Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, provides a period of five years following approval of a drug containing no previously approved active moiety, during which ANDAs for generic versions of those drugs and 505(b)(2) applications referencing those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original drug approval. The Hatch-Waxman Act also provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was supported by new clinical trials other than bioavailability studies that were essential to the approval and conducted by or for the sponsor. During those three years of exclusivity, FDA cannot grant approval of an ANDA or 505(b)(2) application for the protected dosage form, route of administration or combination, or use of that listed drug.

In December 2019, the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 ("CREATES Act") was signed into law. The legislation is intended to address the concern that some brand manufacturers have improperly denied generic and biosimilar product developers access to samples of brand products. The CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on commercially reasonable, market-based terms. If the developer prevails, the court may grant the developer a monetary award up to the brand product's revenue for the period of delay in providing samples.

Biosimilars. The enactment of federal healthcare reform legislation in March 2010 provided a new pathway for approval of follow-on biologics (*i.e.*, biosimilars) under the PHSA. FDA licensure of a biosimilar is dependent upon many factors, including a showing that the proposed biosimilar is "highly similar" to the reference product, notwithstanding minor differences in clinically inactive components, and has no clinically meaningful differences from the reference product in terms of safety, purity, and potency. The types of data ordinarily required in a biosimilar application to show high similarity include analytical data, animal studies (including toxicity studies), and clinical studies (including immunogenicity and pharmacokinetic/pharmacodynamic studies). A biosimilar must seek licensure for a condition of use for which the reference-listed product is licensed.

Furthermore, the PHSA provides that for a biosimilar to be considered "interchangeable" (*i.e.*, the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product), the applicant must make an additional showing that the biosimilar can be expected to produce the same clinical result as the reference product in any given patient, and if the product is administered more than once to a patient, that risks in terms of safety or diminished efficacy of alternating or switching between the biological product and the reference product is no greater than the risk of using the reference product without switching. Although FDA has provided guidance on what information and data an applicant should submit to enable an interchangeability determination, thus far FDA has not licensed any biologic as being interchangeable with its reference product.

The PHSA also provides a period of exclusivity for pioneer biologics. Specifically, FDA may not accept a biosimilar application referencing data from a pioneer biologic (i.e., one approved through a full BLA) until four years have elapsed from the date of first licensure of the pioneer biologic. FDA may not approve a biosimilar application referencing data from a pioneer biologic until 12 years have elapsed since the date of first licensure of the pioneer biologic. There are certain restrictions and limitations on the types of BLAs that are eligible for biologics exclusivity as well as what constitutes the date of first licensure for a pioneer biologic.

In the EU, a pathway for the approval of biosimilars has existed since 2005.

Healthcare compliance laws. In the U.S., commercialization of our drug candidates, if approved, is subject to regulation and enforcement under a number of federal and state healthcare compliance laws administered and enforced by various agencies. These include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits offering or paying anything of value to a person or entity to induce or reward referrals for goods or services reimbursed by a federal healthcare program such as Medicare or Medicaid;

- the federal False Claims Act, which prohibits presenting or causing to be presented a false claim for payment by a federal healthcare program, and which has been interpreted to also include claims caused by improper drug-manufacturer product promotion or the payment of kickbacks;

- a variety of governmental pricing, price reporting, and rebate requirements, including those under Medicaid and the Veterans Health Care Act; and

- the so-called Sunshine Act and certain provisions of the Affordable Care Act, which require that we report to the federal government information on certain financial payments and other transfers of value made to certain health care providers and institutions, as well as certain information regarding our distribution of drug samples.

In addition to these federal law requirements, several U.S. states have enacted similar laws requiring periodic reporting and/or disclosure related to our marketing, sales and other activities, or regulating certain sales and marketing activities, such as provision of meals to certain health care providers. We may also be subject to federal or state privacy laws if we receive protected patient health information.

Similar requirements apply to our operations outside of the U.S. Laws in the U.S. such as the Foreign Corrupt Practices Act prohibit the offering or payment of bribes or inducements to foreign public officials for business, including physicians or other medical professionals who are employees of public healthcare entities. In addition, many non-U.S. jurisdictions in which we operate, or may operate in the future, have their own laws similar to the healthcare compliance laws that exist in the U.S.

Pharmaceutical Pricing and Reimbursement

Overview. In both U.S. and foreign markets, our ability to commercialize our drug candidates successfully, and to attract commercialization partners for our drug candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payers including, in the U.S., managed care organizations and other private health insurers as well as governmental payers such as the Medicare and Medicaid programs. Reimbursement by a third-party payer may depend on a number of factors, including the payer's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Reimbursement by government payers is based on statutory authorizations and complex regulations that may change with annual or more frequent rulemaking, as well as legislative reform measures.

Third-party private and governmental payers are increasingly challenging the prices charged for medicines and examining their cost-effectiveness in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products or drug candidates. Even with the availability of such studies, third-party private and/or governmental payers may not provide coverage and reimbursement for our drug candidates, in whole or in part.

United States. Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. For example, the 2010 Affordable Care Act (the "ACA"), is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Other legislative changes included a two percent across-the-board reduction to Medicare payments to providers, effective April 1, 2013, which, due to subsequent legislative amendments, will begin to increase gradually starting in April 2030, reaching 4 percent in April 2031 and continuing until the reduction ends in October 2031, unless additional congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the period for the government to recover overpayments to providers from three to five years. In December 2017, portions of the ACA dealing with the individual mandate insurance requirement were effectively repealed by the Tax Cuts and Jobs Act of 2017.

Containment of healthcare costs has been a priority of federal, state, and foreign governments, and the prices of drug products have been a focus of this effort. Governments have shown significant interest in implementing cost-containment programs. This interest has resulted in significant proposed and enacted reform measures affecting healthcare reimbursement and drug pricing, including the enactment in August 2022 of significant changes to potential Medicare drug product reimbursement through government negotiation of certain drug prices, as well as manufacturer discount and inflation rebate obligations under the Inflation Reduction Act (the "IRA").

We are unable to predict what additional legislation, regulations, policies or court orders, if any, relating to the healthcare industry or coverage and reimbursement may be enacted or imposed in the future or what effect such legislation, regulations, policies or court orders would have on our business. Any cost-containment measures, including those listed above, or other healthcare system reforms that are adopted could have a material adverse effect on our business prospects and financial operations.

Europe. Governments in the various member states of the EU influence or control the price of medicinal products in their countries through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials or pharmacoeconomic studies that assess the cost-effectiveness of a product or drug candidate relative to currently available therapies or relative to a specified standard. The downward pressure on healthcare costs in general, and prescription medicines in particular, has become very intense and is creating increasingly high barriers to the entry of new products in these markets.

Research and Development

We have built a research and development organization that includes expertise in discovery research, preclinical development, product formulation, analytical and medicinal chemistry, manufacturing, clinical development and regulatory and quality assurance. We operate cross-functionally and are led by an experienced management team. We strive to make disciplined strategic decisions regarding our research and development programs and to limit the risk profile of our product pipeline. We also access relevant market information and key opinion leaders in creating target product profiles and, when appropriate, as we advance our programs to commercialization. We engage third parties on a limited basis to conduct portions of our preclinical research; however, we are not substantially dependent on any third parties for our preclinical research nor do any of these third parties conduct a major portion of our preclinical research. We also engage multiple clinical sites to conduct our clinical trials and rely on third-party contract research organizations ("CROs") to coordinate and execute aspects of clinical trial operations. None of these CROs or clinical sites are responsible for the major portion of our clinical trials and we are not substantially dependent on any one of them.

Employees

As of December 31, 2023, we had 198 full-time employees, 132 of whom are in research and development, 19 of whom are in sales and marketing and 47 of whom are in finance, legal, business development and administration. Our full-time employees include six with M.Ds and 40 with Ph.Ds., of whom five and 39, respectively, are in research and development. None of our employees are represented by a labor union, and we consider our employee relations to be good.

Information about Our Executive Officers and Significant Employees

The following table provides information regarding our executive officers and significant employees as of April 1, 2024:

Name	Age	Position(s)
Executive Officers:		
Gregory A. Demopulos, M.D.	65	President, Chief Executive Officer and Chairman of the Board of Directors
Michael A. Jacobsen	65	Vice President, Finance, Chief Accounting Officer and Treasurer
Peter B. Cancelmo, J.D.	45	Vice President, General Counsel and Secretary
Significant Employees:		
Nadia Dac	54	Vice President, Chief Commercial Officer
Mariana N. Dimitrova, Ph.D.	58	Vice President, Chemistry, Manufacturing and Controls
George A. Gaitanaris, M.D., Ph.D.	67	Vice President, Science and Chief Scientific Officer
Andreas Grauer, M.D.	63	Vice President, Chief Medical Officer
Catherine A. Melfi, Ph.D.	65	Vice President, Regulatory Affairs & Quality Systems and Chief Regulatory Officer
J. Steven Whitaker, M.D., J.D.	68	Vice President, Clinical Development
Peter W. Williams	56	Vice President, Human Resources

Gregory A. Demopulos, M.D. founded our company and has served as our president, chief executive officer and chairman of the board of directors since June 1994. He also served as our chief financial officer and treasurer from January 2009 to October 2013 in an interim capacity and as our chief medical officer from June 1994 to March 2010. Prior to founding Omeros, Dr. Demopulos completed his residency in orthopedic surgery at Stanford University and his fellowship training in hand and microvascular surgery at Duke University. Dr. Demopulos currently serves on the board of trustees of the Smead Funds Trust, an open-end mutual fund company registered under the Investment Company Act of 1940. Dr. Demopulos received his M.D. from the Stanford University School of Medicine and his B.S. from Stanford University. Dr. Demopulos is the brother of Peter A. Demopulos, M.D., a member of our board of directors.

Michael A. Jacobsen has served as our vice president, finance, chief accounting officer and treasurer since October 2013. Prior to joining Omeros, Mr. Jacobsen served as vice president of finance of Sarepta Therapeutics, Inc. from September 2011 to May 2013 and as its chief accounting officer from September 2011 to December 2012. From April 2007 to August 2011, Mr. Jacobsen was vice president and chief accounting officer at ZymoGenetics, Inc. Prior to his service with ZymoGenetics, Mr. Jacobsen held various roles at ICOS Corporation, including senior director of finance and corporate controller. From April 1995 to October 2001, Mr. Jacobsen held vice president of finance or chief financial officer roles at three companies in the software, computer hardware and internet retailing industries, two of which were publicly traded. Mr. Jacobsen is a certified public accountant and received his bachelor's degree in accounting from Idaho State University.

Peter B. Cancelmo, J.D. has served as our vice president, general counsel and secretary since June 2019. He joined Omeros as deputy general counsel in January 2019. Prior to joining Omeros, Mr. Cancelmo was a principal and shareholder at Garvey Schubert Barer, P.C., where he represented clients in the life sciences and other technology industries in mergers, acquisitions, strategic alliances, public and private securities offerings, and a range of other corporate, commercial and financial transactions. He served as chair of the firm's business practice group from 2016 until his departure in December 2018. Mr. Cancelmo previously practiced corporate and transactional law at Davies, Ward, Philips and Vineberg LLP, in New York, and Choate, Hall & Stewart LLP, in Boston. Mr. Cancelmo received his J.D. from Boston University and his B.A. from Saint Michael's College.

Nadia Dac has served as our chief commercial officer since January 2021. Ms. Dac brings nearly three decades of international experience as a strategic commercial leader at large and small biopharmaceutical companies. Prior to joining Omeros, Ms. Dac served as the chief commercial officer at Alder Pharmaceuticals, Inc. (acquired in 2019 by Lundbeck) from April 2019 until June 2020 and as vice president of global specialty commercial development at AbbVie, Inc. from December 2014 to March 2019. She previously served as vice president of marketing at Auxilium Pharmaceuticals, Inc. from May 2013 to September 2014, when the company was acquired by Endo International plc. From 2009 to 2013, Ms. Dac held several roles of increasing responsibility at Novartis AG, including global vice president of neuroscience professional relations prior to her role as vice president of Novartis' multiple sclerosis franchise, and at Biogen Inc., Johnson & Johnson, and Eli Lilly and Company. She holds a B.S. in Marketing from Rutgers University.

Mariana N. Dimitrova, Ph.D., has served as our vice president chemistry, manufacturing, and controls ("CMC") since October 2022. Prior to joining Omeros in this role, Dr. Dimitrova had 20 years of pharmaceutical experience with CMC leadership spanning formulation development, drug product and device development, drug delivery and Human Factors engineering, analytical sciences, process development, and clinical manufacturing. In her career, Dr. Dimitrova contributed to the development of a number of monoclonal antibodies, Fc-fusion proteins, PEG-proteins, bispecific molecules, cytokines, DNA, peptides, and small molecules at Amgen Inc., MedImmune (Astra Zeneca), Biogen, and Jazz Pharmaceuticals. Dr. Dimitrova contributed to the commercialization of nine patient-convenient drug/device combination products for the treatment of autoimmune, respiratory, neurodegenerative, hematology, and infectious diseases. Most recently, from May 2019 to September 2022, Dr. Dimitrova was vice president of product and device development at Akero Therapeutics, developing Fc-FGF21 fusion protein for treatment of NASH. Prior to her industry work, Dr. Dimitrova spent five years in academia, including at the National Heart, Lung, and Blood Institute at the National Institutes of Health and the National Institute of Advanced Industrial Science and Technology (AIST) in Japan. Dr. Dimitrova holds a Ph.D. in Biophysics and Biological Sciences from the Bulgarian Academy of Sciences and the AIST, and a M.S. in Chemistry from Kliment Ohridski University in Bulgaria.

George A. Gaitanaris, M.D., Ph.D. has served as our vice president, science since August 2006 and as our chief scientific officer since January 2012. From August 2003 until our acquisition of nura, inc., in August 2006, Dr. Gaitanaris served as the chief scientific officer of nura, a company that he co-founded, and that developed treatments for central nervous system disorders. From 2000 to 2003, Dr. Gaitanaris served as president and chief scientific officer of Primal, Inc., a biotechnology company that was acquired by nura in 2003. Prior to co-founding Primal, Dr. Gaitanaris served as staff scientist at the National Cancer Institute. Dr. Gaitanaris received his Ph.D. in cellular, molecular and biophysical studies and his M.Ph. and M.A. from Columbia University and his M.D. from the Aristotelian University of Greece.

Andreas Grauer, M.D. has served as our chief medical officer since October 2023. Prior to joining Omeros, Dr. Grauer served as chief medical officer at Federation Bio from October 2021, where he led all clinical activities with a focus on hyperoxaluria and immuno-oncology. From March 2019 to August 2021, Dr. Grauer was chief medical officer of Corcept Therapeutics, Inc., leading its global development organization in the design and execution of clinical programs directed to oncology, neurology, endocrinology, and metabolism indications. From December 2007 to December 2018, Dr. Grauer held several roles of increasing responsibility at Amgen, most recently serving as vice president of global development, therapeutic area head, and co-chair of the franchise steering committee for bone, nephrology and inflammation. Earlier in his career, Dr. Grauer was at Proctor and Gamble Pharmaceuticals where he held roles as global executive medical director for bone and for new technology development. Dr. Grauer received his M.D. from the University of Heidelberg Medical School in Germany, where he also completed his clinical training in internal medicine and endocrinology. He did research in molecular and cellular endocrinology both there and during a post-doctoral fellowship at Baylor College of Medicine. He holds an active associate professorship of medicine at the University of Heidelberg Medical School.

Catherine A. Melfi, Ph.D. has served as our vice president, regulatory affairs and quality systems since October 2012 and has served as our chief regulatory officer since April 2016. Dr. Melfi previously served from January 1996 to September 2012 at Eli Lilly and Company, where she held technical and leadership roles of increasing scope and responsibility, including as senior director and scientific director in global health outcomes and regulatory affairs, respectively. Prior to joining Eli Lilly, Dr. Melfi held various faculty and research positions at Indiana University, including appointments in its Economics Department, in the School of Public and Environmental Affairs, and in the Indiana University School of Medicine. Dr. Melfi received her Ph.D. in Economics from the University of North Carolina - Chapel Hill and B.S. in Economics from John Carroll University.

J. Steven Whitaker, M.D., J.D. has served as our vice president, clinical development since joining Omeros in 2010, and served as our chief medical officer from March 2010 to August 2018 and from November 2019 to October 2023. From May 2008 to March 2010, Dr. Whitaker served as the chief medical officer, vice president of clinical development at Allon Therapeutics, Inc., a biotechnology company focused on developing drugs for neurodegenerative diseases. From August 2007 to May 2008, he served as a medical consultant to Accelerator Corporation, a biotechnology-company investor and incubator. From May 1994 to May 2007, Dr. Whitaker served at ICOS Corporation, which was acquired by Eli Lilly and Company in 2007. At ICOS, he held roles of increasing responsibility in clinical research and medical affairs, most recently as divisional vice president, clinical research as well as medical director of the Cialis® global product team. Dr. Whitaker received his M.D. from the Indiana University School of Medicine, his J.D. from the University of Washington and his B.S. from Butler University.

Peter W. Williams has served as our vice president, human resources since June 2020. Prior to joining Omeros, Mr. Williams served as the senior vice president of human resources at Redbox Automated Retail, LLC from 2016 to 2019, where he led human resources and internal communications functions. From 2013 to 2016, Mr. Williams served as the vice president, HR operations at Outerwall Inc. (Coinstar) and before that he held human resources leadership roles at Coinstar from 2009 to 2013. Prior to 2009, Mr. Williams held human resources leadership roles at various technology and consumer focused companies, including Washington Mutual, Inc., Sterling Commerce, Inc., Expedia, Inc., and Verio, Inc. Mr. Williams received a B.A. in Business Administration and a B.A. in English from the University of Washington.

Corporate Information

We were incorporated in 1994 as a Washington corporation. Our principal executive offices are located at 201 Elliott Avenue West, Seattle, Washington, 98119, and our telephone number is (206) 676-5000. Our website address is www.omeros.com. We make available, free of charge through our investor relations website at investor.omeros.com, our annual report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, including exhibits to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our websites and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with them at www.sec.gov.

ITEM 1A. RISK FACTORS

The risks and uncertainties described below may have a material adverse effect on our business, prospects, financial condition or operating results. In addition, we may be adversely affected by risks that we currently deem immaterial or by other risks that are not currently known to us. You should carefully consider these risks before making an investment decision. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this Annual Report on Form 10-K.

Risks Related to Our Products, Programs and Operations

We have incurred cumulative operating losses since inception. If we are unable to raise additional capital when needed we may be unable to complete the development and commercialization of our drug candidates or to continue our other preclinical development programs.

Our operations have consumed substantial amounts of cash since our incorporation, As of December 31, 2023, we had cash, cash equivalents and short-term investments of $171.8 million. Our cash provided by operations was $74.7 million and our net loss for the year ended December 31, 2023 was $117.8 million. We expect to continue to spend substantial amounts to:

- initiate and conduct clinical trials and manufacture clinical and registration batches for our drug candidates;
- continue our research and development in our programs;
- make principal, interest and fee payments as required under our 5.25% Convertible Senior Notes due 2026 (the "2026 Notes"); and
- commercialize and launch drug candidates for which we may receive regulatory approval.

We expect to continue to incur additional losses until such time as we generate significant revenue from the sale of commercial products or from partnerships. We are unable to predict the extent of any future losses and cannot provide assurance that we will generate sufficient revenue from commercial products in the future to fund our operations fully. If we are unable to generate sufficient revenue from commercialized products or partnership arrangements, we may never become and remain profitable and will be required to raise additional capital to continue to fund our operations. We cannot be certain that additional capital will be available to us on acceptable terms, if at all, when required. Adverse developments to our financial condition or business, as well as disruptions in the global equity and credit markets, may limit our ability to access capital. If we do not raise additional capital when needed through one or more funding avenues, such as debt or equity financings or corporate partnering, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our drug candidates or one or more of our preclinical programs or other research and development initiatives. In addition, we may be required to seek collaborators for one or more of our current or future products at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might be available or to relinquish or license on unfavorable terms our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves. We also may have insufficient funds or otherwise be unable to advance our preclinical programs to a point where they can generate revenue through partnerships, collaborations or other arrangements. Any of these actions could limit the amount of revenue we are able to generate and harm our business and prospects.

Failure to obtain and maintain regulatory approval in the U.S. or in foreign jurisdictions would prevent us from commercializing and marketing our drug candidates.

The regulatory process is subject to substantial agency discretion and risks, including those described herein and elsewhere in these "Risk Factors." In October 2021, we received a CRL from FDA regarding our BLA for narsoplimab for the treatment of TA-TMA. In the CRL, FDA expressed difficulty in estimating the treatment effect of narsoplimab in TA-TMA and asserted that additional information would be needed to support regulatory approval. We appealed FDA's decision to issue the CRL through a formal dispute resolution process that concluded in late 2022. Although our appeal was denied, the decision identified a potential path for resubmission of the BLA based on inclusion of certain additional information and analyses. Consistent with subsequent interactions with FDA's review division regarding resubmission of the BLA, we submitted to FDA in the fall of 2023 an analysis plan to assess already existing clinical trial data, existing data from an historical control population available from an external source, data from the narsoplimab expanded access program, and data directed to the mechanism of action of narsoplimab. We are having ongoing discussions with the agency regarding the proposed analysis plan and are currently unable to estimate when we will submit the BLA. Additionally, the requirements for resubmission of our BLA may be costly, require significant time and may not result in approval. Ultimately, we cannot guarantee that FDA will ever approve narsoplimab for the treatment of TA-TMA or any other indication.

We also intend to market outside the U.S. any of our drug candidates that are approved in the future. In order to market our products in non-U.S. jurisdictions, we or our partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The regulatory approval procedure varies among countries and can involve additional testing and data review. The requirements governing marketing authorization, the conduct of clinical trials, pricing and reimbursement vary from country to country. Approval by FDA does not ensure approval by the EMA, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by FDA. The time required to obtain regulatory approval outside the U.S. and EU may differ from that required to obtain FDA or EU approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these "Risk Factors" and we may not obtain foreign regulatory approvals on a timely basis, or at all. In addition, even if we were able to obtain regulatory approval for a product in one or more foreign jurisdictions, we may need to complete additional requirements to maintain that approval and our ability to market the product in the applicable jurisdiction.

If any product that we develop and commercialize does not receive adequate coverage or reimbursement from governments and/or private payers our prospects for revenue and profitability would suffer.

The success of any product that we or our third-party business partners commercialize in the future will depend heavily on the pricing, availability and duration of adequate coverage or reimbursement for any such product from government, private and other third-party payers, both in the U.S. and in other countries.

There may be significant delays in obtaining coverage or reimbursement for newly approved products, and we may not be able to provide data sufficient to be granted adequate coverage or reimbursement. Even when a payer determines that a product is eligible for reimbursement, coverage may be limited to the uses of a product that are either approved by FDA (or, in other countries, the relevant country's regulatory agency) and/or appear in a recognized drug compendium, or other conditions may apply. Moreover, eligibility for coverage does not mean that any product will be reimbursed at a rate that allows us to make a profit or at a rate that covers our costs, including research, development, manufacturing, sales and distribution. Increasingly, government and private third-party payers that reimburse for healthcare services and products are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products, which could adversely impact the pricing of our products. Any reduction in reimbursement from Medicare, including as a result of the Inflation Reduction Act, or other government programs may result in a similar reduction in payments from private payers. Pricing may also be adversely affected by changes in the terms, scope and/or complexity of government pricing requirements. Even if we achieve coverage or reimbursement for a product, the initial rate or method at which the product will be reimbursed could become unfavorable to us at the time reimbursement is initiated or in the future or may be of a limited duration. In addition, obtaining acceptable coverage and reimbursement from one payer does not guarantee that we will obtain similar acceptable coverage or reimbursement from another payer.

In non-U.S. jurisdictions, we must obtain separate reimbursement approvals and comply with related foreign legal and regulatory requirements. In some countries, including those in the EU, our products may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time and expenditure of resources after the receipt of marketing approval for a product. We provide no assurances that the price of any product in one or more of these countries or regions will allow us to make a profit or cover our costs, including research, development, manufacturing, sales and distribution, and as a result we may decide to delay, potentially indefinitely, initiating sales in the particular country or region.

If the reimbursement or pricing that we are able to obtain and maintain for any product that we develop and commercialize is inadequate, is significantly delayed or is subject to overly restrictive conditions, our ability to generate revenue, attain profitability and/or commercialize our drug candidates may be impaired and there could be a material adverse effect on our business, financial condition, results of operations and growth prospects and the trading price of our stock could decline.

Our ability to meet our future capital requirements is partially dependent on certain milestone and royalty payments that we are eligible to receive based on Rayner's sales of OMIDRIA, and, if sales of OMIDRIA are less than anticipated and/or Rayner is unable to expand sales of OMIDRIA outside the U.S., our financial condition and results of operations may be materially adversely affected, the price of our common stock may decline and we may be unable to access needed capital on favorable terms, or at all.

In February 2024, we sold to DRI an expanded interest in OMIDRIA royalties payable by Rayner. Pursuant to the Amendment with DRI, DRI is entitled to receive all royalties on U.S. net sales of OMIDRIA between January 1, 2024 and December 31, 2031. Omeros retains the right to receive all royalties payable by Rayner on any net sales of OMIDRIA outside the U.S. payable from and after January 1, 2024, as well as all royalties on global net sales of OMIDRIA payable from and after December 31, 2031. We received $115.5 million in cash upon closing of the Amendment. Additionally, we are eligible under the Amendment to receive two milestone payments of up to $27.5 million each, payable in January 2026 and January 2028, respectively, based on achievement of certain thresholds for U.S. net sales of OMIDRIA.

The royalty rate payable by Rayner on net sales of OMIDRIA is currently 30% in the United States and 15% outside the U.S. The royalty rate is subject to further reduction to 10% of U.S. net sales upon the occurrence of certain events, including during any specific period in which OMIDRIA is no longer eligible for separate payment. The availability of royalties from Rayner and/or milestone payments from DRI is dependent on Rayner's net sales of OMIDRIA and may be of lesser magnitude than anticipated or may not become payable at all. We cannot provide assurance that royalty income from Rayner and/or milestone payments from DRI, if they become payable, will be a meaningful source of capital in the future. Sales-based royalty income and milestone payments may be affected by any number of factors, including:

- Rayner's ability to successfully market and sell OMIDRIA in the U.S.;
- whether, and to what extent, Rayner is able to expand sales of OMIDRIA outside the U.S.;
- pricing, coverage and reimbursement policies of government and private payers such as Medicare, Medicaid, the U.S. Department of Veterans Affairs, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- a lack of acceptance by physicians, patients and other members of the healthcare community;
- interruptions in the supply of OMIDRIA;
- the availability, relative price and efficacy of the product as compared to alternative treatment options or branded, compounded or generic competing products;
- an unknown safety risk; and
- changed or increased regulatory restrictions in the U.S., EU and/or other foreign territories.

Our operating results are unpredictable and may fluctuate.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- the extent and magnitude of certain payments to which we may be entitled based on Rayner's net sales of OMIDRIA may be affected by the extent of coverage and reimbursement for OMIDRIA, market acceptance of the product and Rayner's ability to execute an effective sales strategy;
- the extent of any payments received from any collaboration agreements or development funding arrangements that we may enter into from time to time, as well as the extent of any payments that we are required to make under existing or future collaboration and license agreements, which may include sales-based royalties and milestone payments based on the achievement of development, regulatory and sales milestones and may vary significantly from quarter to quarter;
- the timing, cost and level of investment in our research and development activities as well as expenditures we may incur to acquire or develop additional technologies, drug candidates, or in preparation for potential commercialization of our drug candidates; and
- whether we are able to obtain marketing approval for any of our drug candidates, the extent and timing of revenue from sales of any such approved product and the magnitude and timing of expenses associated with the manufacturing and sale of any such approved product.

Any of these risk factors, should one or more occur, could adversely affect our results of operations and financial condition and cause the trading price of our stock to decline.

We are subject to extensive government regulation and the failure to comply with these regulations may have a material adverse effect on our operations and business.

Both before and after approval of any product, we and our suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the U.S. and other countries, covering, among other things, testing, manufacturing, quality control, clinical trials, post-marketing studies, reporting, risk management plans, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions: warning letters; unanticipated expenditures; delays in approval or refusal to approve a drug candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties; adverse publicity; and disruptions to our business. Further, government investigations into potential violations of these laws would require us to expend considerable resources and face adverse publicity and the potential disruption of our business even if we are ultimately found not to have committed a violation.

Obtaining FDA approval of our drug candidates requires substantial time, effort and financial resources and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on any of our drug candidates on a timely basis, if at all. As was the case with our BLA for narsoplimab in TA-TMA, with respect to which FDA issued a CRL, even after collaborating closely with FDA or regulators with corollary responsibilities in jurisdictions outside the U.S. regarding the contents of a marketing application a regulator may decide that the design of our clinical trials or clinical data collection protocols as actually run, or our resulting data, are insufficient for approval of our drug candidates. FDA or other regulators may require us to run additional preclinical, clinical or other studies or perform additional work related to chemistry, manufacturing and controls. In addition, we, FDA or an independent institutional review board or ethics committee may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are or would be exposed to an unacceptable health risk or because of the way in which the investigators on whom we rely carry out the trials. We are subject to extensive government regulation of the testing of our investigational products, including the requirement that we conduct all of our clinical trials in accordance with FDA's GCP requirements and similar requirements outside of the U.S. If we are unable to comply with these requirements, if we are required to conduct additional trials or to conduct other testing of our drug candidates beyond that which we currently contemplate for regulatory approval, if we are unable to complete our clinical trials or other testing successfully, or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may face substantial additional expenses, be delayed in obtaining marketing approval for our drug candidates or may never obtain marketing approval.

We are also required to comply with extensive governmental regulatory requirements after a product has received marketing authorization. Governing regulatory authorities may require post-marketing studies that may negatively impact the commercial viability of a product. Once on the market, a product may become associated with previously undetected adverse effects and/or may develop manufacturing difficulties. We are required to comply with other post-marketing requirements including cGMPs, advertising and promotion restrictions, pharmacovigilance requirements including risk management activities, reporting and recordkeeping obligations, and other requirements. As a result of any of these or other problems or failure to comply with our regulatory obligations, a product's regulatory approval could be withdrawn, which could harm our business and operating results. In addition, we must maintain an effective healthcare compliance program in order to comply with U.S. and other laws applicable to marketed drug products and, in particular, laws (such as the Anti-Kickback Statute, the False Claims Act and the Sunshine Act) applicable when drug products are reimbursed by a federal or state healthcare program. U.S. laws such as the Foreign Corrupt Practices Act prohibit the offering or payment of bribes or inducements to foreign public officials, including potentially physicians or other medical professionals who are employees of public healthcare entities in jurisdictions outside the U.S. In addition, many countries have their own laws similar to the healthcare compliance laws that exist in the U.S. Implementing and maintaining an effective compliance program requires the expenditure of significant time and resources. If we are found to be in violation of any of these laws, we may be subject to significant penalties, including but not limited to civil or criminal penalties, damages and fines as well as exclusion from government healthcare programs.

We may face difficulties from changes to current regulations as well as future legislation.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Any reduction in reimbursement from Medicare resulting from the IRA or other legislative or policy changes or from other government programs may result in a similar reduction in payments from private payers. These healthcare reforms and the implementation of any future cost containment measures or other reforms may prevent us from being able to generate sufficient revenue, attain and/or maintain profitability or commercialize our drug candidates. We cannot be sure whether additional legislative changes will be enacted, whether existing legislation will be implemented, interpreted or enforced as anticipated or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on our drug candidates, if any, may be.

We have no internal capacity to manufacture commercial or clinical supplies of our drug candidates and intend to continue to rely solely on third-party manufacturers, which could significantly limit or delay our clinical trials or regulatory submissions and may negatively impact our financial conditions and results of operations. If we are unable to establish relationships with contract manufacturers that have sufficient manufacturing capacity available to meet our needs, or if the contract manufacturers that we rely on experience difficulties manufacturing and supplying our drug candidates, or fail FDA or other regulatory inspections, then our clinical trials or regulatory submissions may be significantly limited or delayed or we may have inadequate supply to meet demand for any product that we commercialize in the future.

We rely and intend to continue to rely on third-party manufacturers to produce quantities of clinical drug supplies of our drug candidates that are needed for clinical trials and to support NDAs, BLAs, or similar applications to regulatory authorities seeking marketing approval for our drug candidates, as well as to produce inventory of our drug candidates for commercial use in anticipation of marketing approval. Global demand for contract manufacturing is volatile and the available supply of contract manufacturing capacity is limited and unpredictable. We cannot provide any assurance that we will be able to enter into or maintain these types of arrangements on commercially reasonable terms, or at all, or that manufacturing arrangements will meet our requirements. Our contract manufacturers previously have and may in the future require us to place orders or make other financial commitments several years in advance of manufacturing commencement based on forecasts of our long-term commercial supply requirements for drug candidates that have not yet received, and may never receive, regulatory approval. We may be required to pay significant cancellation fees or other financial penalties in connection with the withdrawal or cancellation of any binding order for manufacturing that we later determine is not needed. The fees or other financial obligations that we may incur in connection with withdrawn or cancelled orders may be material and any such financial penalty would negatively impact our financial condition and results of operations.

If we or one of our manufacturers were to terminate one of these arrangements early, or the manufacturer was unable to supply product quantities sufficient to meet our requirements, we would be required to transfer manufacturing to an approved alternative facility and/or establish additional manufacturing and supply arrangements. We may also need to establish additional or replacement manufacturers, potentially with little or no notice, in the event that one of our manufacturers fails to comply with FDA and/or other pharmaceutical manufacturing regulatory requirements. Even if we are able to establish additional or replacement manufacturers, identifying these sources and entering into definitive supply agreements and obtaining regulatory approvals may require a substantial amount of time and cost and may create a shortage of the product. It can take several years to qualify and validate a new contract manufacturer, and we cannot guarantee that we would be able to complete in a successful and timely manner the appropriate validation processes or obtain the necessary regulatory approvals for one or more additional or replacement manufacturers. Such alternate supply arrangements may not be available on commercially reasonable terms, or at all. Additionally, if we are unable to engage multiple suppliers to manufacture our products, we may have inadequate supply to meet demand for our product.

In addition, narsoplimab, OMS906 and OMS1029 are biologic drug products and other drug candidates from certain of our programs, including but not limited to MASP-2 and MASP-3, could be biologic drug products. We do not have the internal capability to produce biologics for use in clinical trials or on a commercial scale. There are only a limited number of manufacturers of biologic drug products and we may be unable to enter into agreements on commercially reasonable terms with a sufficient number of them to meet clinical or commercial demand, if at all. The regulatory requirements for commercial supply are more stringent than for clinical supply and we cannot guarantee that a contract manufacturer producing drug product for clinical trials will be able to complete successfully the appropriate validation processes or obtain the necessary regulatory approvals for marketing approval and commercial supply in a timely manner or at all.

Our contract manufacturers may encounter difficulties with formulation, manufacturing, supply chain and/or release processes that could result in delays in clinical trials and/or regulatory submissions or that could impact adversely the commercialization of our products or drug candidates, as well as in the initiation of enforcement actions by FDA and other regulatory authorities. For example, our manufacturers are required to comply with FDA's GMP requirements and are subject to periodic inspections by FDA. If our manufacturers are unable to comply with FDA requirements, they may be unable to meet our supply needs. These difficulties also could result in the recall or withdrawal of a product from the market or a failure to have adequate supplies to meet market demand. If the safety or manufacturing quality of any drug candidate supplied by contract manufacturers is compromised due to one or more of those contract manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to maintain regulatory approval to run clinical trials or to obtain and maintain regulatory approval for one or more of our drug candidates, which would harm our business and prospects significantly.

Any significant delays in the manufacture and/or supply of clinical or commercial supplies could materially harm our business, financial condition, results of operations and prospects.

Ingredients, excipients, test kits and other materials necessary to manufacture our drug candidates may not be available on commercially reasonable terms, or at all, which may adversely affect the development and commercialization of our drug candidates.

We and our third-party manufacturers must obtain from third-party suppliers the APIs, excipients, and/or other raw materials plus primary and secondary packaging materials necessary for our contract manufacturers to produce our drug candidates for our clinical trials and, to the extent approved or commercialized, for commercial distribution. Although we have entered or intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of APIs, excipients, test kits and materials for our drug candidates, we have not entered into agreements for the supply of all such ingredients, excipients, test kits or materials, and we may be unable to secure all such supply agreements or guarantees on commercially reasonable terms, if at all. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients, excipients, test kits or materials in a timely manner or in the quantities required. Further, if we or our third-party manufacturers are unable to obtain APIs, excipients, test kits and materials as necessary for our clinical trials or for the manufacture of commercial supplies of our drug candidates, if approved, potential regulatory approval or commercialization would be delayed, which would materially and adversely affect our ability to generate revenue from the sale of our drug candidates.

We may be unable to advance clinical development of narsoplimab for treatment of COVID-19 and, even if successful, we may be unable to manufacture narsoplimab in sufficient quantities.

Narsoplimab has been used to treat critically ill COVID-19 patients under our compassionate use program with highly positive results and, in an analysis of the randomized population in the narsoplimab treatment arm of I-SPY COVID-19 trial, the addition of narsoplimab to standard-of-care treatment of critically ill COVID-19 patients resulted in a mortality benefit. Notwithstanding these results, we may determine not to continue clinical development of narsoplimab for COVID-19 and/or further clinical evaluation of narsoplimab for the treatment of COVID-19 may not be feasible as a result of a number of factors, including decreasing rates of severe illness in patients with COVID-19 and the availability of alternative preventive or therapeutic agents for COVID-19. Additionally, the results of the I-SPY-COVID-19 trial may be not be viewed by regulators, government officials and others as strong evidence of narsoplimab's efficacy in the treatment of severe COVID-19 because the narsoplimab treatment arm of the I-SPY-COVID-19 trial was terminated prior to accrual of the maximum of 125 patients on the basis of analysis in a pre-consented population in which substantial bias was detected. Also, contract manufacturing capacity and supplies of raw materials necessary for the production of narsoplimab are limited and we may be unable to secure the large-scale manufacturing capacity from third parties necessary to manufacture narsoplimab in sufficient quantities to enable broad availability of narsoplimab for COVID-19 patients. These risks could limit our ability to develop or commercialize a therapeutic for COVID-19.

If our clinical trials or clinical protocols are delayed, suspended or terminated, we may be unable to develop our drug candidates on a timely basis, which would adversely affect our ability to obtain regulatory approvals, increase our development costs and delay or prevent commercialization of approved products.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials or clinical data collection protocols that will cause regulatory agencies, institutional review boards or ethics committees, or us to delay our clinical trials or suspend or delay the analysis of the data from those trials. Clinical trials and clinical data protocols have been, and in the future can be, delayed for a variety of reasons, including:

- discussions with FDA, the EMA or other foreign authorities regarding the scope or design of our clinical trials or clinical data collection protocols;
- delays or the inability to obtain required approvals from institutional review boards, ethics committees or other responsible entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials, collecting data from enrolled patients or collecting historical control data for any reason including disease severity, trial or data collection protocol design, study eligibility criteria, patient population size (*e.g.*, for orphan diseases or for some pediatric indications), proximity and/or availability of clinical trial sites for prospective patients, availability of competing therapies and clinical trials, regional differences in diagnosis and treatment, perceived risks and benefits of the product or drug candidate, disruptions due to external events or conditions affecting the localities or regions in which our clinical trials are conducted, such as terrorism, political crises, natural disasters, war and wartime conditions, such as those in Ukraine, which has affected the operation of our clinical trials of OMS906, or outbreaks of contagious disease such as the COVID-19 pandemic, which previously slowed enrollment in our clinical trials of narsoplimab;
- lower than anticipated retention rates of patients in clinical trials;
- the need to repeat or conduct additional clinical trials as a result of inconclusive or negative results, failure to replicate positive early clinical data in subsequent clinical trials, failure to deliver an efficacious dose of a drug candidate, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol or to follow GCPs or other study requirements, an unacceptable study design or other problems;
- adverse findings in clinical or nonclinical studies related to the safety of our drug candidates in humans;
- an insufficient supply of drug candidate materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of drug candidate materials for FDA and foreign regulatory approval;
- an unfavorable inspection or review by FDA or other regulatory authority of a clinical trial site or records of any clinical investigation;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials;
- the suspension by a regulatory agency of a trial by imposing a clinical hold; or
- the amendment of clinical trial or data collection protocols to reflect changes in regulatory requirements and guidance or other reasons as well as subsequent re-examination of amendments to clinical trial or data collection protocols by regulatory agencies, institutional review boards or ethics committees.

In particular, because PNH and C3G, the indications for which our ongoing clinical trials are evaluating OMS906, are rare conditions, we have opened and expect to continue opening clinical sites in Ukraine and other countries that may be affected by armed conflict or political instability or that have not been traditionally established as centers for clinical research. Like Ukraine, some of these areas have been, and may continue to be, affected by such conflict, instability and/or health infrastructure challenges. Enrollment and retention of patients in, or the ability to receive results from, these clinical trials could be disrupted by the existing conditions in these areas or other geopolitical or macroeconomic developments. If patients withdraw from our trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols, if we are unable to resupply the drugs to clinical sites on schedule, or if our trial results are otherwise disrupted or disputed due to such conditions and developments, the integrity of data from our trials may be compromised or not accepted by FDA or other regulatory authorities, which would represent a significant setback for the development of this drug candidate.

In addition, our clinical trial or development programs have been, and in the future may be, suspended or terminated by us, FDA or other regulatory authorities, or institutional review boards or ethics committees due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- our failure to comply with our regulatory obligations as a sponsor of clinical research, such as adverse event reporting, control of study drug, adequate study monitoring, and other obligations;
- the failure to remove a clinical hold in a timely manner, if at all;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks;
- inability to deliver an efficacious dose of a drug candidate; or
- lack of adequate funding to continue the clinical trial or development program, including as a result of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and/or increased expenses associated with the services of our contract research organizations ("CROs"), or other third parties.

If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to file for regulatory approval or conduct additional clinical trials on the schedule we currently anticipate. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a drug candidate. Any delays in completing our clinical trials could increase our development costs, could slow down our product development and regulatory submission process, could delay our receipt of product revenue and could make it difficult to raise additional capital. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products, potentially harming our business.

Because we have a number of drug candidates and development programs, we may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications for which there is a greater likelihood of obtaining regulatory approval and that may be more profitable, if approved.

We have limited resources and must focus on the drug candidates and clinical and preclinical development programs that we believe are the most promising. As a result, we may forgo or delay the pursuit of opportunities with other drug candidates or other indications that later prove to have greater commercial potential and may not be able to progress development programs as rapidly as otherwise possible. Further, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug through collaboration, license or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

Our drug candidates may not successfully complete clinical development or be suitable for successful commercialization or generation of revenue through partnerships, and our preclinical programs may not produce drug candidates that are suitable for clinical trials.

We must successfully complete preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before commencing clinical trials for any drug candidate. Many pharmaceutical and biological drug candidates do not successfully complete preclinical testing. There can be no assurance that positive results from preclinical studies will be predictive of results obtained from subsequent preclinical studies or clinical trials.

Even if preclinical testing is successfully completed, we cannot be certain that any drug candidates that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials, and safety and/or efficacy outcomes of early clinical trials may not be consistent with outcomes of subsequent clinical trials. There can be no assurance that we will be able to successfully commercialize our current or future drug candidates or to meet our expectations with respect to revenues or profits from such products.

We may incur substantial costs as a result of commercial disputes, claims, litigation or other legal proceedings relating to our business operations, especially with regard to patent and other intellectual property rights, and such costs or an adverse outcome in such a proceeding may adversely affect our financial condition, results of operations and/or stock price.

Our business involves numerous commercial contractual arrangements, important intellectual property rights, potential product liability, uncertainties with respect to clinical development, manufacture and regulatory approvals and other aspects that create heightened risks of disputes, claims and legal proceedings. These include claims that may be faced in one or more jurisdictions related to the safety of our drug candidates, the development of our drug candidates, our ability to obtain regulatory approval for our drug candidates, our expectations regarding product development and regulatory approval, sales and marketing practices, commercial disputes including with contract manufacturers, competition, environmental matters, employment matters and other matters. These matters could consume significant time and resources, even if we are successful. Many of our competitors and contractual counterparties are significantly larger than we are and, as a result, may be able to sustain the costs of complex litigation more effectively than we can because they have substantially greater resources. In addition, we may pay damage awards or settlements or become subject to equitable remedies that could, individually or in the aggregate, have a material negative effect on our financial condition, results of operations or stock price. Any uncertainties resulting from the initiation and continuation of any litigation also could have a material adverse effect on our ability to raise the capital necessary to continue our operations.

We may initiate or become subject to litigation regarding patents and other intellectual property rights. Patent infringement litigation involves many complex technical and legal issues and its outcome is often difficult to predict and the risk involved in doing so can be substantial. Manufacturers of generic or biosimilar drugs could seek approval to market a generic or biosimilar version of our products or challenge our intellectual property rights with respect to our drug candidates.

Further, our industry has produced a large number of patents and it is not always clear which patents cover various types of products or methods of use. A third party may claim that we or our contract manufacturers are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in the alleged infringing activity, including making, using or selling our drug candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we, or our contract manufacturers, are infringing the third party's patents and would order us or our contractors to stop the activities covered by the patents. In addition, if we or our contract manufacturers are found to have violated a third party's patent, we or our contract manufacturers could be ordered to pay damages to the other party. We have agreed or may in the future agree to indemnify our contract manufacturers against certain patent infringement claims and thus may be responsible for any of their costs associated with such claims and actions. If we were sued for patent infringement, we would need to demonstrate that our drug candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we might be unable to do this. Proving invalidity, in particular, is difficult since it requires clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our drug candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our drug candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the U.S. Patent and Trademark Office or by a court or other trier of fact in the U.S., or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the U.S. or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our drug candidates and/or materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. In addition, to the extent that we are unable to obtain and maintain patent protection for one of our drug candidates or in the event that such patent protection expires or is limited to method of use patent protection, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product or drug candidate for follow-on indications.

We also may rely on trade secrets to protect our technologies or drug candidates, especially where we do not believe patent protection is appropriate or obtainable. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our indebtedness and liabilities could limit the cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operations.

As of December 31, 2023, we had $213.2 million total aggregate principal amount of our 2026 Notes outstanding, and we had approximately $1.3 million of outstanding finance lease obligations. We may incur additional indebtedness to meet future financing needs. Our existing and future indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- requiring a substantial portion of our cash flow from operations to service and repay our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our ability to obtain additional financing;
- limiting our flexibility to plan for, or react to, changes in our business;

- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon any conversion of the Convertible Notes;
- placing us at a possible competitive disadvantage with competitors that are less leveraged than we are or have better access to capital; and
- increasing our vulnerability to adverse economic and industry conditions.

Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Convertible Notes, depends on our future performance, which is subject to many factors, including, economic, financial, competitive and other circumstances beyond our control. Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the Convertible Notes, and our cash needs may increase in the future. In addition, future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

Competitors may develop products that are less expensive, safer or more effective, or which may otherwise diminish or eliminate the success of any products that we may commercialize.

We may not achieve commercial success if our competitors, many of which have significantly more resources and experience than we have, market products that are safer, more effective, less expensive or faster to reach the market than any products that we may develop and commercialize. Our competitors also may market a product that proves to be unsafe or ineffective, which may affect the market for future product we are developing, regardless of the safety or efficacy of our product. The failure of any future product that we may market to compete effectively with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, our financial condition and our results of operations.

The loss of members of our management team could substantially disrupt our business operations.

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies other than on the life of Gregory A. Demopulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, without having a readily available and appropriate replacement could delay the execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

We rely on highly skilled personnel and, if we are unable to retain or motivate key personnel or hire qualified personnel, we may not be able to maintain our operations or grow effectively.

Our performance is largely dependent on the talents and efforts of highly skilled individuals, many of whom possess specialized expertise that may be difficult to replace. Our future success depends on our continuing ability to identify, hire, develop, motivate and retain highly skilled personnel for all areas of our organization. If we are unable to hire and train a sufficient number of qualified employees for any reason, we may not be able to implement our current initiatives or grow effectively. We maintain a rigorous, highly selective and time-consuming hiring process. We believe that our approach to hiring has significantly contributed to our success to date. If we do not succeed in attracting qualified personnel and retaining and motivating existing personnel, our existing operations may suffer and we may be unable to grow effectively.

We may encounter difficulties managing our growth, which could delay our business plans or adversely affect our results of operations.

To manage our future growth, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit, train and retain qualified personnel. We may not be able to implement necessary business processes and systems, recruit, train and retain additional qualified personnel and otherwise manage the growth of our enterprise due to factors such as limited financial resources and competition for qualified personnel within local, national and international markets. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Additionally, our inability to manage growth effectively could cause our operating costs to exceed our forecasts.

Product liability claims may damage our reputation and, if insurance proves inadequate, these claims may harm our business.

We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product's safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with commercialization of our drug candidates. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain or maintain such insurance on acceptable terms for any product we bring to market. Further, our product liability insurance coverage may not provide coverage for or may be insufficient to reimburse us for any or all expenses or losses we may suffer. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

We rely on third parties to conduct portions of our preclinical research and clinical trials. If these third parties do not perform as contractually required or otherwise expected, or if we fail to adequately supervise or monitor these parties, we may not be able to obtain regulatory approval for or commercialize our drug candidates.

We rely on third parties, such as CROs, medical and research institutions and clinical investigators, to conduct a portion of our preclinical research, assist us in conducting our clinical trials or to conduct third party-sponsored clinical trials of our drug candidates. Nonetheless, we are responsible for confirming that our preclinical research and clinical trials are conducted in accordance with applicable regulations, the relevant trial protocol and within the context of approvals by an institutional review board or ethics committee, and we may not always be successful in ensuring such compliance. Our reliance on these third parties does not relieve us of responsibility for ensuring compliance with FDA and other regulations and standards for conducting, monitoring, recording and reporting the results of preclinical research and clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical and clinical development processes may be extended, delayed, suspended or terminated, and we may not be able to commercialize or obtain regulatory approval for our drug candidates.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected products or product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, which could enable our competitors to obtain access to the same technologies licensed to us.

If we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product or product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

As a non-accelerated filer, we are no longer required to comply with the auditor attestation requirements of the Sarbanes-Oxley Act.

As of December 31, 2023, we are a non-accelerated filer under the Exchange Act and, therefore, we are no longer required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. Therefore, our internal controls over financial reporting will not receive the level of review provided by the process relating to the auditor attestation included in annual reports of issuers that are subject to the auditor attestation requirements. In addition, we cannot predict if investors will find our common stock less attractive because we are not required to comply with the auditor attestation requirements. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the trading price for our common stock may be negatively affected.

Our share repurchase program could affect the price of our common stock and increase volatility and may be suspended or terminated at any time, which may result in a decrease in the trading price of our common stock.

In November 2023, our board of directors authorized a share repurchase program to repurchase, from time to time, up to $50.0 million of our outstanding shares of common stock in the open market, including under trading plans established pursuant to Rule 10b5-1 and Rule 10b-18 under the Exchange Act, or in privately negotiated transactions. The share repurchase program does not have a fixed expiration date, may be suspended or discontinued at any time, and does not obligate us to acquire any amount of our common stock. The timing, manner, price, and amount of any repurchases may be determined by us at our discretion and will depend on a variety of factors, including business, economic and market conditions, prevailing stock prices, corporate and regulatory requirements, and other considerations. As of March 26, 2024, approximately $33.8 million remained available to repurchase of our outstanding shares of common stock under the share repurchase program.

Repurchases pursuant to our share repurchase program could affect our stock price and increase its volatility. The existence of a share repurchase program could also cause our stock price to be higher than it would be in the absence of such a program and could potentially reduce the market liquidity for our common stock. There can be no assurance that any repurchases will enhance shareholder value, because the market price of our common stock may decline below the levels at which we repurchased our common stock. Although our share repurchase program is intended to enhance long-term shareholder value, short-term stock price fluctuations could reduce the share repurchase program's effectiveness.

General Risk Factors Related to our Business

Cyber-attacks or other failures in telecommunications or information technology systems could result in information theft, data corruption and significant disruption of our business operations.

We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. While we have not experienced any previous cybersecurity incidents that have had a material adverse effect on or company, we cannot provide assurance that a future cybersecurity incident will not occur or that it would not materially affect our business, results of operations or financial condition. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline.

During the 12-month period ended December 31, 2023, the closing price of our stock ranged from as high as $7.57 per share and as low as $1.08 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to numerous factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing shareholders would experience further dilution.

To the extent that we raise additional funds in the future by issuing equity securities, our shareholders would experience dilution, which may be significant and could cause the market price of our common stock to decline significantly. In addition, approximately 15.3 million shares of common stock were subject to outstanding options as of December 31, 2023 and may become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements. As of December 31, 2023, we also had approximately 8.8 million additional shares of common stock reserved for future issuance under our employee benefit plans that are not subject to outstanding options. Further, to the extent we issue common stock upon conversion of the Convertible Notes, such conversion would dilute the ownership interests of existing stockholders despite the expected reduction of such dilution as a result of the capped call transactions that we entered into in connection with the original issuances of the Convertible Notes. If the holders of outstanding options or warrants elect to exercise some or all of them, or if the shares subject to our employee benefit plans are issued and become eligible for sale in the public market, or we issue common stock upon conversion of the Convertible Notes, our shareholders would experience dilution and the market price of our common stock could decline.

If we or the third parties upon whom we rely are adversely affected by natural disasters or other events, our business continuity and disaster recovery plans may not adequately protect us from such interruptions.

Any unplanned event, such as flood, fire, explosion, earthquake, tsunami, extreme weather condition, power shortage, power outage, telecommunication failure, or other natural or man-made accidents or incidents could disrupt our operations. If a natural disaster or other event were to occur that prevents us from using all or a significant portion of our headquarters, that damages critical infrastructure, such as the manufacturing facilities of our third-party manufacturers, or that otherwise disrupts operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We may not carry sufficient business interruption insurance to compensate us for all losses that may occur. The disaster recovery and business continuity plans we have in place may not be adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of a natural disaster or other event, which could have a material adverse effect on our business, and we could potentially lose valuable data and other items. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

Anti-takeover provisions in our charter documents and under Washington law could make an acquisition of us, which may be beneficial to our shareholders, difficult and prevent attempts by our shareholders to replace or remove our current management.

Provisions in our articles of incorporation and bylaws and under Washington law may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on shareholder actions by less than unanimous written consent, restrictions on the ability of shareholders to fill board vacancies and the ability of our board of directors to issue preferred stock without shareholder approval. In addition, because we are incorporated in Washington, we are governed by the provisions of Chapter 23B.19 of the Washington Business Corporation Act, which, among other things, restricts the ability of shareholders owning 10% or more of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We have never declared or paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

Our business requires significant funding. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Therefore, we currently do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a rise in the market price of our common stock, which is uncertain and unpredictable, will be the sole source of potential gain for shareholders in the foreseeable future, and an investment in our common stock for dividend income should not be relied upon.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

Omeros maintains a cybersecurity risk management program that is designed to assess, identify, manage and respond to risks from cybersecurity threats in a robust manner. This program shares certain common methodologies, reporting channels and governance processes applicable to our management of other risk areas, such as legal, compliance, strategic, operational and financial risk.

We utilize a range of internal and external resources to assess and identify cybersecurity threats and vulnerabilities. We access and utilize information drawn from a range of publications, reports and services to assess our cybersecurity risk profile, develop awareness of emerging cybersecurity threats and threat actors and identify risk factors that are particularly relevant to the biotechnology and pharmaceutical sector and to our company. We also work with third parties that assist us to identify, assess and manage cybersecurity risks, including external auditors, consulting firms, managed security service providers and penetration testing firms.

We have implemented and maintain various technical, physical and organizational measures, processes, standards and/or policies designed to manage and mitigate material risks from cybersecurity threats. These include data encryption, network security controls, access controls, physical security, asset management, system hardening, vulnerability management and patching and continuous monitoring of information technology systems and network telemetry data using a variety of manual and automated tools and systems designed to detect and respond to suspicious or unusual activity. We maintain systems and plans for business continuity and disaster recovery and have implemented tools and procedures for cybersecurity incident detection and response. We also operate a cybersecurity training program for employees that includes required webinars and deployment of simulated phishing and similar attacks in which threat actors utilize social engineering to gain access to company systems.

We take a risk-weighted approach to mitigation of cybersecurity risks associated with use of third-party service providers. Based on an assessment of the cybersecurity risks presented by a given third-party service provider, we seek to minimize third-party cybersecurity risk on a case-by-case basis, generally through a combination of due diligence in the selection of qualified vendors and the imposition of contractual terms requiring the vendor to maintain specified cybersecurity safeguards and/or to accept financial responsibility for security breaches occurring within the vendor's area of responsibility.

We are not aware of any specific risks from specific cybersecurity threats, and have not experienced any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect our company, including our business strategy, results of operations or financial condition. While we continue to invest in the security and resiliency of our information technology systems and to enhance our cybersecurity controls and processes, we cannot provide assurance that a future cybersecurity incident will not occur or that it would not materially affect our company. Please see Item 1A of Part I of this Annual Report under the heading "Risk Factors" for additional discussion about risks related to cybersecurity.

Governance

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. Pursuant to its charter, the audit committee of our board of directors is responsible for the oversight of management's efforts to address cybersecurity risk. Management reports to the audit committee on cybersecurity risk matters periodically, typically twice annually. These reports normally address matters such as: the evolving cybersecurity risk environment and the emergence of new threats; outcomes and learnings from penetration testing, security audits or vulnerability assessments; evaluation of existing controls, tools and procedures and progress on implementation of any new initiatives to manage and mitigate cybersecurity risk. In addition, members of our board of directors regularly engage in discussions with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs.

Our cybersecurity risk management program is managed by our Director of Information Technology (the "IT Director"), whose team is responsible for leading enterprise-wide cybersecurity strategy, policy, standards, architecture and processes. The IT Director has been with the organization since 2007, has a post-graduate degree in Information Security, and is a member of InfraGard, a partnership between the Federal Bureau of Investigation and members of the private sector for the protection of U.S. critical infrastructure. The IT Director is informed about and monitors prevention, detection, mitigation and remediation of cybersecurity risks and incidents through various means, which may include, among other things, briefings with dedicated internal security personnel, threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us, and alerts and reports produced by security tools deployed in our information technology environment. The IT Director provides periodic reports on cybersecurity risk to the audit committee of our board of directors, as well as our chief executive officer and other members of our senior management as appropriate.

ITEM 2. PROPERTIES

We lease approximately 113,060 square feet for our principal office and laboratory space in the building located at 201 Elliott Avenue West, Seattle, Washington ("the Omeros Building"), which includes 7,245 square feet of laboratory space that we are subleasing to third parties. The lease term for our space is through November 2027. We also have two options to extend the lease term, each by five years. The annual base rent due under the lease for our principal office and laboratory space is $7.0 million for 2024, $7.1 million for 2025, $6.9 million for 2026, and $5.9 million for 2027. In addition, we are responsible for paying our proportionate share of the building's utilities, taxes, insurance and maintenance as well as a property management fee.

We believe that our facilities are sufficient for our anticipated near-term needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, in the ordinary course of business, we may be involved in various claims, lawsuits and other proceedings. As of the date of filing of this Annual Report on Form 10-K, we were not involved in any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on The Nasdaq Global Market under the symbol "OMER."

Holders

As of March 28, 2024, there were approximately 57,942,695 shares of our common stock outstanding, which were held by 84 holders of record.

Dividends

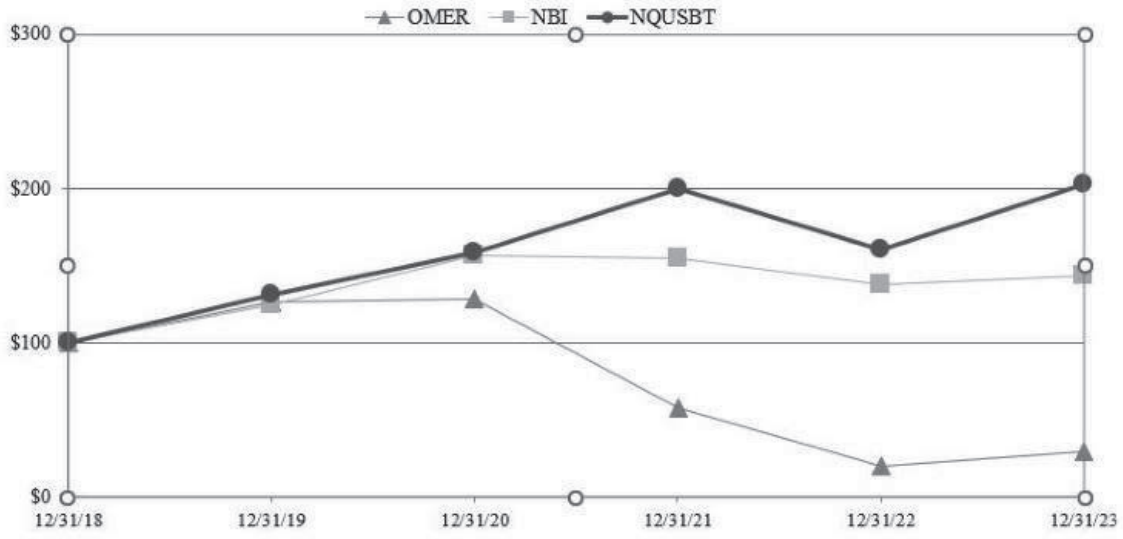
We have never declared or paid any cash dividends on our capital stock. We expect to retain all available funds and future earnings to fund the development and growth of our business and we do not anticipate paying any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

We did not sell any equity securities that were not registered under the Securities Act during the three fiscal years ended December 31, 2023.

Stock Performance Graph

The following graph compares the cumulative total shareholder return for our common stock (OMER), the Nasdaq Biotechnology Index (NBI) and the Nasdaq U.S. Benchmark TR Index (NQUSBT) for the period beginning December 31, 2018 and ending December 31, 2023. This graph assumes that $100 was invested on December 31, 2018 in our common stock, the Nasdaq Biotechnology Index and the Nasdaq U.S. Benchmark TR Index. It also assumes that any dividends were reinvested. The data shown in the following graph are not necessarily indicative of future stock price performance.



The foregoing information shall not be deemed to be "soliciting material" or to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to liability under that Section. In addition, the foregoing information shall not be deemed to be incorporated by reference into any of our filings under the Exchange Act or the Securities Act, except to the extent that we specifically incorporate this information by reference.

Issuer Purchases of Equity Securities

The following table provides information regarding our repurchases of our common stock during the quarter ended December 31, 2023:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (1)	Maximum Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs (1) (In thousands)
10/01/23 – 10/31/23	—	$ —	—	$ —
11/01/23 – 11/30/23	579,387	1.98	579,387	48,852
12/01/23 – 12/31/23	1,224,757	2.80	1,224,757	45,424
Total	1,804,144	$ 2.54	1,804,144	

(1) On November 9, 2023, our board of directors approved an indefinite term share repurchase program under which we may repurchase from time to time up to $50.0 million of our common stock in the open market, including under trading plans established pursuant to Rule 10b5-1 and Rule 10b-18 under the Exchange Act, or in privately negotiated transactions. As of March 26, 2024, approximately $33.8 million remained available for repurchase of our outstanding shares of common stock under the share repurchase program.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the audited annual consolidated financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. For further information regarding forward-looking statements, please refer to the special note regarding forward-looking statements at the beginning of this Annual Report on Form 10-K. Throughout this discussion, unless the context specifies or implies otherwise, the terms "Company," "we," "us" and "our" refer to Omeros Corporation and our wholly owned subsidiaries.

Overview

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting immunologic disorders including complement-mediated diseases, cancers related to the dysfunction of the immune system, and addictive and compulsive disorders.

Complement Inhibitor Programs

The complement system plays a role in the body's inflammatory response and becomes activated as a result of tissue damage or trauma or microbial pathogen invasion. Inappropriate or uncontrolled activation of the complement system can cause diseases characterized by serious tissue injury. Three main pathways can activate the complement system: classical, lectin, and alternative. Omeros is focused on development of therapeutics to treat diseases associated with the lectin and/or alternative pathways of complement. Omeros is developing antibodies as well as small-molecule inhibitors of key enzymes known to be centrally involved in the in activation of the targeted pathway of complement.

Lectin Pathway / MASP 2

MASP-2, is a novel pro-inflammatory protein target that is the effector enzyme of the lectin pathway and is required for the function of this pathway. Omeros is developing antibodies and small-molecule inhibitors of MASP-2 as potential therapeutics for diseases in which the lectin pathway has been shown to contribute to significant tissue injury and pathology. When not treated, these diseases are typically characterized by significant end-organ damage, such as kidney or central nervous system injury. Importantly, inhibition of MASP-2 has been demonstrated not to interfere with the antibody-dependent classical complement activation pathway, a critical component of the acquired immune response to infection.

The lead drug candidate in our MASP-2 inhibitor program is narsoplimab (OMS721), a proprietary, patented human monoclonal antibody targeting MASP-2, the effector enzyme of the lectin pathway of complement. Clinical development of narsoplimab is currently focused primarily on TA-TMA and development efforts are also directed to COVID-19, ARDS and PASC. We are also developing OMS1029, a long-acting, next-generation antibody targeting MASP-2 and the lectin pathway which we expect will be well-suited to indications requiring long-term, chronic administration. In addition, we are advancing our orally administered small-molecule MASP-2 inhibitor through IND-enabling studies. For more information, see Part I, Item 1 in this Annual Report on Form 10-K under the heading "Complement Inhibitor Programs: *MASP-2 Program – Lectin Pathway Disorders*".

Alternative Pathway / MASP-3

Our pipeline of clinical-stage complement-targeted therapeutic candidates also includes OMS906, a proprietary, patented monoclonal antibody targeting MASP-3, the key activator of the alternative pathway of complement. We believe OMS906 has the potential to treat a wide range of alternative pathway-related diseases and that its attributes favorably differentiate OMS906 from other marketed and in-development alternative pathway inhibitors. Clinical development of OMS906 is currently focused on rapidly advancing to Phase 3 clinical trials in multiple alternative pathway-related disorders, including PNH and C3G. We have multiple ongoing Phase 2 clinical trials evaluating OMS906 in these indications. For more information, see Part I, Item 1 in this Annual Report on Form 10-K under the heading "Complement Inhibitor Programs: *MASP-3 Program – Alternative Pathway Disorders*".

PDE7 Inhibitor Programs

Our PDE7 inhibitor program, which we refer to as OMS527, comprises multiple PDE7 inhibitor compounds and is based on our discoveries of previously unknown links between PDE7 and any addiction or compulsive disorder, and between PDE7 and any movement disorders. In April 2023, we were awarded a grant from the National Institute on Drug Abuse, part of the National Institutes of Health, to develop our lead orally administered PDE7 inhibitor compound, for which we have successfully completed a Phase 1 study, for the treatment of cocaine use disorder ("CUD"). The grant amount, a total of $6.69 million over three years, is intended to support preclinical cocaine interaction/toxicology studies to assess safety of the therapeutic candidate in the presence of concomitant cocaine administration, as well as an in-patient, placebo-controlled clinical study evaluating the safety and effectiveness of OMS527 in adults with CUD who receive concurrent intravenous cocaine. The preclinical study is intended to provide the toxicology data necessary to support the human study of OMS527 in CUD. The toxicology study is underway and is expected to be completed in late 2024. Additionally, with investigators at Emory University, we are also evaluating OMS527 as a potential treatment for levodopa-induced dyskinesia, a common and debilitating side effect of long-term levodopa dosing in patients with Parkinson's disease. For more information, see Part I, Item 1 in this Annual Report on Form 10-K under the heading "Other Clinical Programs: *PDE7 Inhibitor Programs – OMS527*".

Pre-clinical Programs

We are advancing preclinical research on potential molecular and cellular therapies for cancer. On the molecular front, we have developed novel biologic platforms to target cancer cells specifically and kill them directly or indirectly through the potentiation of the immune system. Our novel molecules combine tumor antigens with a potent adjuvant and show high levels of killing in cancer cells. We believe that some of these molecules could function as therapeutic vaccines against a broad range of tumors, potentially transforming treatment of both solid tumors and hematologic cancers. On the cellular front, we are evaluating novel approaches for both adoptive T cell and CAR T therapies. We have identified specific T cell signaling pathways, which, once inhibited, significantly and preferentially enhance the expansion of memory T cells that distinctively recognize and efficiently kill tumor cells. We continue to develop and validate our novel approach, which we believe could improve response rates for patients receiving either engineered or native T cell therapies for liquid or solid tumors.

OMIDRIA Sale and Royalty Monetization Transactions

We previously developed and commercialized OMIDRIA® (phenylephrine and ketorolac intraocular solutions) 1%/0.3%, which is approved by FDA for use during cataract surgery or intraocular ("IOL") replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. We marketed OMIDRIA in the U.S. from the time of its commercial launch in 2015 until December 2021.

On December 23, 2021, we sold our commercial product OMIDRIA and certain related assets, including inventory and prepaid expenses, to Rayner. Rayner paid us $126.0 million in cash at the closing and we retained all outstanding accounts receivable, accounts payable, and accrued expenses as of the closing date.

Under the Asset Purchase Agreement, we were entitled to receive a $200.0 million Milestone Payment within 30 days following an event (the "Milestone Event") that establishes separate payment for OMIDRIA for a continuous period of at least four years when furnished in the ambulatory surgery center ("ASC") setting. The Milestone Event occurred in December 2022 and we recorded a $200.0 milestone receivable. We received the Milestone Payment together with accrued interest in February 2023.

Under the Asset Purchase Agreement, the occurrence of the Milestone Event in December 2022 triggered a reduction in the U.S. royalty rate from 50% to 30% on OMIDRIA net sales until the expiration or termination of the last issued and unexpired U.S. patent, which we expect to occur no earlier than 2035. Upon the occurrence of certain events described in the Asset Purchase Agreement, including during any specific period in which OMIDRIA is no longer eligible for certain separate payment (i.e., becomes included in the packaged payment rate for the surgical procedure) under Medicare Part B, the U.S. base royalty rate would be reduced to 10%. Pursuant to legislation enacted in late 2022, we expect separate payment for OMIDRIA under Medicare Part B to extend until at least January 1, 2028.

As a result of the OMIDRIA divestiture, the results of OMIDRIA operations have been reclassified to net income from discontinued operations, net of tax in our consolidated statements of operations and comprehensive income (loss) and excluded from continuing operations for all periods presented.

On September 30, 2022, we sold to DRI an interest in a portion of our future OMIDRIA royalty receipts and received $125.0 million in cash consideration which we recorded as an OMIDRIA royalty obligation on our consolidated balance sheet. Interest expense is recorded as a component of continuing operations. The aggregate amount of royalties to which DRI is entitled under this arrangement is capped at $188.4 million.

On February 1, 2024, we sold to DRI an expanded interest in the OMIDRIA royalties pursuant to the terms of an amended and restated royalty purchase agreement dated February 1, 2024 (the "Amendment"). We received $115.5 million in cash upon closing of the Amendment. The Amendment eliminated the caps on royalty payments effective beginning in the first quarter of 2024, and provides that DRI will now receive all royalties on U.S. net sales of OMIDRIA payable between January 1, 2024 and December 31, 2031. DRI is entitled to payment only to the extent of royalty payments that are payable on U.S. net sales of OMIDRIA on or before December 31, 2031 and DRI has no recourse to our assets other than its interest in the OMIDRIA royalties. Omeros retains the right to receive all royalties payable by Rayner on any net sales of OMIDRIA outside the U.S. payable from and after January 1, 2024, as well as all royalties on global net sales of OMIDRIA payable from and after December 31, 2031. In addition to the cash consideration received at closing, the Amendment also entitles us to receive a milestone payment ranging between $10.0 million and $27.5 million if U.S. net sales of OMIDRIA reach applicable thresholds ranging between a total of $156.0 million and $160.0 million for any period of four consecutive quarters ending prior to January 1, 2026 as well as a separate milestone payment ranging between $8.0 million and $27.5 million if U.S. net sales of OMIDRIA reach applicable thresholds ranging between a total of $181.0 million and $185.0 million for any period of four consecutive quarters ending prior to January 1, 2028. See Part II, Item 8, "Note 8 – OMIDRIA Royalty Obligation" to our Consolidated Financial Statements in this Annual Report on Form 10-K for additional information.

As of December 31, 2023, we had cash, cash equivalents and short-term investments of $171.8 million and, in February 2024, we received $115.5 million from DRI.

Results of Operations

Research and Development Expenses

Our research and development expenses can be divided into three categories: direct external expenses, which include clinical research and development and preclinical research and development activities; internal, overhead and other expenses; and stock-based compensation expense. Direct external expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations prior to receiving regulatory approval for a drug candidate, CROs, clinical trial sites, collaborators, licensors and consultants. Pre-clinical research and development includes costs prior to beginning Phase 1 studies in human subjects. Internal, overhead and other expenses primarily consist of costs for personnel, overhead, rent, utilities and depreciation. The discontinued operations of OMIDRIA relates to the costs of drug manufacturing stability, quality control testing and costs of employees and consultants. The following table illustrates our expenses associated with these activities:

	Year Ended Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Continuing research and development expenses:			
Direct external expenses:			
Clinical research and development:			
MASP-2 program - OMS721 (narsoplimab)	$ 35,352	$ 50,408	$ 48,806
MASP-3 program - OMS906	22,853	6,304	7,005
MASP-2 program - OMS1029	6,249	2,687	—
Other	153	442	555
Total clinical research and development	64,607	59,841	56,366
Preclinical research and development	5,172	7,254	15,031
Total direct external expenses	69,779	67,095	71,397
Internal, overhead and other expenses	40,337	39,503	40,587
Stock-based compensation expenses	4,754	6,123	6,791
Total continuing research and development expenses	114,870	112,721	118,775
Discontinued research and development expenses	—	—	3,839
Total research and development expenses	$ 114,870	$ 112,721	$ 122,614

Clinical research and development expenses increased $4.8 million between 2023 and 2022. The $16.5 million increase in OMS906 development costs was due to an increase in manufacturing and Phase 2 clinical trial costs and a $5.0 million development milestone paid in 2023 under a technology license agreement. The $3.6 million increase in OMS1029 expense was primarily due to costs associated with initiation of human trials and other clinical development costs, i.e. the transition from preclinical to clinical development status in the third quarter of 2022. These increases were offset by decreased narsoplimab manufacturing costs during 2023.

The $3.5 million increase in clinical research and development costs between 2022 and 2021 was primarily due to the advancement of OMS1029 from preclinical status to clinical research and development status on initiation of the Phase 1 clinical trial in the third quarter of 2022. Additionally, we incurred increased narsoplimab drug manufacturing costs in 2022 compared to the prior year. These costs were partially offset by reduced costs in our OMS906 program resulting from the completion of toxicology study work in the second quarter of 2022.

Preclinical research and development expenses decreased $2.1 million in 2023 compared to 2022, primarily due to the migration of OMS1029 from preclinical to clinical research and development status during the third quarter of 2022, offset by an increase in preclinical oncology research costs during 2023. The $7.8 million decrease in 2022 over 2021 in preclinical research and development expenses was primarily due to the migration of OMS1029 from preclinical to clinical research and development status during the third quarter of 2022.

The changes in stock-based compensation expense between the three covered years were due to the valuations of employee stock options.

We expect our overall research and development costs in 2024 to be similar to 2023, driven by commercial narsoplimab manufacturing costs expected to be incurred prior to FDA approval of TA-TMA, increases in OMS906 clinical and manufacturing costs, and decreases in OMS721 clinical costs. Our accounting policy is to expense all manufacturing costs related to drug candidates until regulatory approval is reasonably assured in either the U.S. or Europe.

At this time, we are unable to estimate with certainty the longer-term costs we will incur in the continued development of our drug candidates due to the inherently unpredictable nature of our preclinical and clinical development activities. Clinical development timelines, the probability of success and development costs can differ materially as new data become available and as expectations change. Our future research and development expenses will depend, in part, on the preclinical or clinical success of each drug candidate as well as ongoing assessments of each program's commercial potential. In addition, we cannot forecast with precision which drug candidates, if any, may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

We are required to expend substantial resources in the development of our drug candidates due to the lengthy process of completing clinical trials and seeking regulatory approval. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could delay our generation of product revenue and increase our research and development expenses.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses are comprised primarily of salaries, benefits and stock-based compensation costs for sales, marketing and administrative personnel who are not directly engaged in research and development. Costs also include marketing and selling expenses, professional and legal services, general corporate costs and an allocation of our occupancy costs.

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Continuing selling, general and administrative expenses:			
Selling, general and administrative expenses, excluding stock-based compensation expense	$ 42,520	$ 42,626	$ 46,688
Stock-based compensation expense	7,140	8,042	8,154
Total continuing selling, general and administrative expenses	49,660	50,668	54,842
Discontinued selling, general and administrative expenses	—	—	25,428
Total selling, general and administrative expenses	$ 49,660	$ 50,668	$ 80,270

Continuing selling, general and administrative expenses, excluding stock-based compensation expense, decreased $4.1 million between 2022 and 2021 primarily related to reduced spending on pre-commercialization sales and marketing activities which were higher in 2021 as we prepared for the then anticipated approval and commercial launch of narsoplimab for the treatment of TA-TMA.

The changes in stock-based compensation expense between the three covered years were due to the valuations of employee stock options.

Our selling, general and administrative expenses for 2024 will be highly dependent on whether narsoplimab receives U.S. marketing approval for treatment of TA-TMA. If TA-TMA is approved in 2024, we expect to hire a field sales force and initiate commercial launch activities which will increase our selling, general and administrative expenses. If narsoplimab is not approved in 2024, our selling, general and administrative expenses are expected to decrease in 2024.

Interest Expense

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Interest expense	$ 30,844	$ 22,702	$ 19,669

Interest expense is primarily comprised of interest and amortization of debt discount and issuance costs related to our convertible senior notes and interest on our DRI royalty obligation (see Part II, Item 8, "Note 6 – Convertible Senior Notes" and "Note 8 – OMIDRIA Royalty Obligation" to our Consolidated Financial Statements in this Annual Report on Form 10-K for additional information).

Interest expense increased $8.1 million in 2023 compared to 2022 primarily due to incurring interest from our DRI royalty obligation for the full year. Interest expense increased $3.0 million in 2022 compared to 2021 primarily due to interest incurred from our DRI royalty obligation only in the fourth quarter of 2022.

Interest and Other Income

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Interest and other income	$ 16,342	$ 4,062	$ 1,740

The $12.3 million increase in interest and other income between 2023 and 2022 was primarily due to holding higher average cash and investment balances than in the prior year as a result of receiving a $200.0 million Milestone Payment from Rayner in February 2023. The $2.3 million increase in interest and other income between 2022 and 2021 was primarily attributable to obtaining significantly higher interest rates on our cash and investments in 2022.

We expect interest and other income in 2024 to be less than 2023 primarily due to lower average cash and investment balances during 2024.

Gain on Early Extinguishment of Convertible Senior Notes

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Gain on early extinguishment of convertible senior notes	$ 4,112	$ —	$ —

In December 2023, we repurchased $9.1 million par value of our 2026 Notes at a discount, realizing a $4.1 million non-cash gain on extinguishment.

Net Income from Discontinued Operations, Net of Tax

On December 23, 2021, we sold our commercial drug, OMIDRIA, to Rayner. As a result of the OMIDRIA divestiture, the results of OMIDRIA operations have been reclassified to discontinued operations for all periods presented.

Net income from OMIDRIA discontinued operations, net of tax is shown below:

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Product sales, net	$ —	$ —	$ 110,735
Costs and expenses	—	—	30,631
Gross margin	—	—	80,104
Gain on sale of OMIDRIA	—	—	305,648
Milestone income	—	200,000	—
Interest on OMIDRIA contract royalty asset	15,315	18,634	—
Remeasurement adjustments	41,167	14,457	—
Other income	1,087	307	1,035
Income before income tax	57,569	233,398	386,787
Income tax expense (1)	(462)	(3,952)	(1,006)
Net income from discontinued operations, net of tax	$ 57,107	$ 229,446	$ 385,781

(1) For further discussion of income tax expense, please refer to Part II, Item 8, “Note 13 – Income Taxes” to our Consolidated Financial Statements in this Annual Report on Form 10-K.

Gain on the Sale of OMIDRIA

On December 23, 2021, we completed the sale of OMIDRIA to Rayner and received $126.0 million in cash at the closing. Additionally, we recorded an OMIDRIA contract royalty asset of $184.6 million for the rights to receive future royalties from Rayner on OMIDRIA net sales. The sale of OMIDRIA qualified as an asset sale under GAAP.

Rayner's U.S. net sales of OMIDRIA for the years ended December 31, 2023 and 2022 were $135.3 million and $130.9 million, respectively. We earned royalties of $40.6 million and $65.4 million on OMIDRIA net sales for the years ended December 31, 2023 and 2022, respectively, which we recorded as a reduction from the OMIDRIA contract royalty asset. The decrease in royalty earnings between the years ended December 31, 2023 and 2022 was due to a reduction of our royalty rate on U.S. net sales of OMIDRIA from 50% to 30% upon achievement of the $200.0 million Milestone Event. (For further discussion of discontinued operations, please refer to Part II, Item 8, "Note 7 – Discontinued Operations – Sale of OMIDRIA" to our Consolidated Financial Statements in this Annual Report on Form 10-K).

Milestone Income

The Milestone Event occurred in December 2022, entitling us to receive a Milestone Payment of $200.0 million from Rayner. We received the Milestone Payment together with accrued interest in February 2023.

Interest Income

During the years ended December 31, 2023 and 2022, we recorded $15.3 million and $18.6 million, respectively, of income in discontinued operations, representing interest income on the outstanding OMIDRIA contract royalty asset at an implied interest rate of 11.0%.

Remeasurement Adjustments

During the years ended December 31, 2023 and 2022, we recorded $41.2 million and $14.5 million, respectively, of remeasurement adjustments. The $26.7 million increase in 2023 was primarily attributable to assigning a greater probability of achieving higher royalty earnings on net sales of OMIDRIA as supported by our most recent transaction with DRI, which closed on February 1, 2024.

Income Tax Expense

For the years ended December 31, 2023, 2022 and 2021, we recorded state income tax expense of $0.5 million, $4.0 million and $1.0 million, respectively, which could not be offset by prior period net operating losses and tax credit carryforwards.

Financial Condition - Liquidity and Capital Resources

As of December 31, 2023, we had cash, cash equivalents and short-term investments of $171.8 million. For the year ended December 31, 2023, our cash provided by operations was $74.7 million and our net loss was $117.8 million. In February 2024, we received $115.5 million upon the sale to DRI of our U.S. OMIDRIA royalty receipts payable between January 1, 2024 and December 31, 2031.

Historically, we have incurred net losses from continuing operations and negative operating cash flows. We have not yet established an ongoing source of revenue sufficient to cover our operating costs; therefore, we potentially need to continue to raise additional capital to accomplish our business plan and to retire our outstanding convertible senior notes due in 2026. We plan to continue to fund our operations for at least the next twelve months with our existing cash and investments and the $115.5 million we received in February 2024 from DRI. We have a sales agreement to sell shares of our common stock, from time to time, in an “at the market” equity offering facility through which we may offer and sell shares of our common stock equaling an aggregate amount up to $150.0 million. Should it be determined to be strategically advantageous, we could pursue debt financings as well as public and private offerings of our equity securities, similar to those we have previously completed, or other strategic transactions, which may include licensing a portion of our existing technology. Should it be necessary to manage our operating expenses, we could also reduce our projected cash requirements by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

Cash Flow Data

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Selected cash flow data			
Cash provided by (used in):			
Operating activities	$ 74,726	$ (86,483)	$ (109,722)
Investing activities	$ 27,454	$ (127,564)	$ 193,710
Financing activities	$ (106,084)	$ 124,248	$ 6,319

Operating Activities. Net cash provided by operating activities for the year ended December 31, 2023 increased by $161.2 million compared to the same period in 2022. This increase was primarily due to collecting the $200.00 million Milestone Payment from Rayner in the current year and a $15.3 increase in accounts payable and accrued expenses. These increases were offset by a $26.7 million change in the remeasurement of the OMIDRIA contract royalty asset, $8.7 million related to the accretion of interest on U.S. government treasury bills and a $4.1 million gain on the early extinguishment of a portion of our 2026 Notes.

Net cash used in operating activities for the year ended December 31, 2022 decreased by $23.2 million compared to the same period in 2021. This change was primarily due to a decrease in net income of $146.8 million as we recognized $310.6 million of non-cash gain from the sale of OMIDRIA in the prior year and a change in cash collections of $124.7 million through accounts receivables and royalty earnings. This was offset by a $200.0 million milestone receivable recognized in 2022 as well as $35.6 million in non-cash charges and $29.7 million of accounts payable, accrued expenses and other.

Investing Activities. Net cash provided by investing activities increased $155.0 million during 2023 compared to 2022 driven by net proceeds from the purchase and sale of investments.

Net cash provided by investing activities decreased $321.3 million during 2022 compared to 2021. This was driven by a $194.5 million decrease in net proceeds from the purchase and sale of investments and recognizing $126.0 million in proceeds from the sale of OMIDRIA in 2021.

Financing Activities. Net cash used in financing activities decreased $230.3 million during 2023 compared to the prior year. The decrease was primarily due to receiving $125.0 million in 2022 in connection with selling a portion of our OMIDRIA royalties to DRI and extinguishing $95.0 million of our 6.25% convertible senior notes (the "2023 Notes"). In addition, we paid $4.9 million to retire $9.1 million par value of our 2026 Notes and repurchased $4.7 million of our common stock through a stock repurchase program in 2023.

Net cash provided by financing activities increased $117.9 million during 2022 compared to the prior year. The increase was primarily due to receiving cash proceeds of $125.0 million in connection with the sale of a portion of our OMIDRIA royalties to DRI, which was partially offset by a reduction in stock option exercises of $8.0 million during 2022.

Contractual Obligations and Commitments

Operating Leases

We lease our office and laboratory space in The Omeros Building under a lease agreement with BMR - 201 Elliott Avenue LLC. The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of December 31, 2023, the remaining aggregate non-cancelable rent payable under the initial term of the lease, excluding common area maintenance and related operating expenses, was $26.9 million.

We have finance leases for certain laboratory and office equipment that have lease terms expiring through November 2026.

Convertible Notes

For more information regarding the convertible senior notes extinguished in mid-November 2023 and convertible senior notes due in February 2026, see Part II, Item 8, “Note 6 - Convertible Senior Notes”.

OMIDRIA Royalty Obligation

For more information regarding the OMIDRIA Royalty Obligation, see Part II, Item 8, “Note 8 - OMIDRIA Royalty Obligation”.

Goods & Services

We have certain non-cancelable obligations under other agreements for the acquisitions of goods and services associated with the manufacturing of our drug candidates, which contain firm commitments. As of December 31, 2023, our aggregate firm commitments were $25.8 million.

We may be required, in connection with in-licensing or asset acquisition agreements, to make certain royalty and milestone payments and we cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. Therefore, such payments are not included in the table above. For information regarding agreements that include these royalty and milestone payment obligations, see Part II, Item 8, “Note 10 - Commitments and Contingencies” to our Consolidated Financial Statements in this Annual Report on Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our consolidated financial statements in conformity with U.S. generally accepted accounting principles (“GAAP”) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from those estimates. An accounting policy is considered critical if it is important to a company’s financial condition and results of operations and if it requires the exercise of significant judgment and the use of estimates on the part of management in its application. Although we believe that our judgments and estimates are appropriate, actual results may differ materially from our estimates. For a summary of our critical accounting policies, see Part II, Item 8, “Note 2 - Significant Accounting Policies” to our Consolidated Financial Statements in this Annual Report on Form 10-K.

We believe the following to be our critical accounting policies because they are both important to the portrayal of our financial condition and results of operations and they require critical judgment by management and estimates about matters that are uncertain:

- revenue recognition;
- OMIDRIA royalties and contract asset accounting;
- OMIDRIA royalty obligation accounting;
- research and development expenses related to clinical trials;
- accounting for convertible debt issuances, primarily related to fair valuing debt and issuance costs; and
- stock-based compensation, primarily related to our fair value assumptions.

If actual results or events differ materially from those contemplated by us in making these estimates, our reported financial condition and results of operations for future periods could be materially affected.

Product Revenue Recognition

Prior to the December 23, 2021 sale of OMIDRIA to Rayner, we recorded revenue from product sales when the product was delivered to our wholesalers and title for the product was transferred. Product sales were recorded net of wholesaler distribution fees and estimated chargebacks, rebates, returns and purchase-volume discounts. Accruals or allowances were established for these deductions in the same period when revenue was recognized, and actual amounts incurred were offset against the applicable accruals or allowances. We reflected each of these accruals or allowances as either a reduction in the related accounts receivable or as an accrued liability depending on how the amount was expected to be settled.

OMIDRIA Royalties, Milestones and Contract Royalty Assets

We have rights to receive future royalties from Rayner on OMIDRIA net sales at royalty rates that vary based on geography and certain regulatory contingencies. Therefore, future OMIDRIA royalties are treated as variable consideration. To measure the OMIDRIA contract royalty asset, we used the expected value approach which is the discounted sum of probability-weighted royalty payments, we would receive using a range of potential outcomes, to the extent that it is probable that a significant reversal in the amount of cumulative income recognized will not occur. Our calculations take the net present value of the sum to arrive at the OMIDRIA contract royalty asset stated on the balance sheet. We revalued the contract royalty asset to reduce the applicable royalty percentage from 50% to 30%, as required under the Asset Purchase Agreement following the occurrence of the December 2022 event triggering the $200.0 million Milestone Payment. Royalties earned will be recorded as a reduction to the OMIDRIA contract royalty asset. The amount recorded in discontinued operations in future periods will reflect interest earned on the outstanding OMIDRIA contract royalty asset and any amounts received different from the expected royalties recorded at closing. The OMIDRIA contract royalty asset is subject to changes in net sales of OMIDRIA. All else being equal, a 10% decrease or increase in net sales results in a $16.8 million change in value of the OMIDRIA contract royalty asset, resulting in a potential contract royalty asset valued within the range of $151.3 million to $184.9 million. Changes in net sales could occur due to various risks such as competitors entering the market, changes in the standard of care for cataract patients and loss of separate payment status for OMIDRIA. In determining the value of the OMIDRIA contract royalty asset, we have considered all of these factors. The OMIDRIA contract royalty asset will be re-measured periodically using the expected value approach based on actual results and future expectations. Any required adjustment to the OMIDRIA contract royalty asset will be recorded in discontinued operations.

We receive monthly royalty payments based on Rayner's OMIDRIA product sales in accordance with the Asset Purchase Agreement. Upon the closing of the Asset Purchase Agreement, we determined the expected minimum net present value of future OMIDRIA royalty receipts and recognized the amount as a gain on the sale of OMIDRIA in discontinued operations on our income statement and as an OMIDRIA contract royalty asset on our balance sheet. To determine the OMIDRIA contract royalty asset, we used the expected value approach which is based on the sum of probability-weighted payments we would receive using a range of potential outcomes at an effective interest rate of 11%. The contract royalty asset excludes any revenue which potentially may be reversed in the event of an over estimation.

OMIDRIA Royalty Obligations

The sale of any portion of our OMIDRIA royalty receipts is treated as a liability on our consolidated balance sheet to the extent that any of our royalties are capped, as this does not result in the transfer of a participating interest. We amortize royalty obligation liabilities over the term of the arrangement using the effective interest method and classify interest expense as a component of continuing operations.

To the extent our estimates of future royalties are less than previous estimates, we will adjust the carrying amount of the royalty obligation to the present value of the revised estimated cash flows, discounted at the original effective interest rate utilizing the cumulative catch-up method. The adjustment would be recognized as a component of net income (loss) from continuing operations.

Research and Development Expenses

Research and development costs are comprised primarily of:

- contracted research and manufacturing costs;
- clinical study costs;
- costs of personnel, including salaries, benefits and stock compensation;
- consulting arrangements;
- depreciation and an allocation of our occupancy costs; and
- other expenses incurred to sustain our overall research and development programs.

Contracted research and manufacturing costs are primarily incurred in the development and production of our drug candidates. Prior to approval, our estimates are based on the timing of services provided. We record accrued expenses equal to our estimated expense in excess of amount invoiced by the suppliers.

Clinical trial expenses are estimated on a cost per patient that varies depending on the clinical trial site. As actual costs become known to us, we adjust our estimates; these changes in estimates may result in understated or overstated expenses at any given point in time.

Convertible Debt Issuances

On January 1, 2021, we adopted Accounting Standards Update ("ASU") 2020-06, *Debt—Debt with Conversion Options* (Subtopic 470.20 *and Derivatives and Hedging—Contracts in Entity's Own Equity* (Subtopic 815-40) on a modified retrospective basis. ASU 2020-06 removes the separate liability and equity accounting for our convertible senior notes. As of January 1, 2021, we account for our convertible senior notes wholly as debt. Prior to January 1, 2021, we accounted for convertible debt that may be settled wholly or partially in cash upon conversion as having both a liability component (debt) and an equity component (conversion option). The cash conversion guidance applies as the embedded conversion features meet the requirements for a derivative scope exception for instruments that are both indexed to an entity's own stock and classified in stockholders' equity in the balance sheet. Principal cash proceeds from the instrument are allocated first to the liability component based on the fair value of non-convertible debt using the income and market-based approaches to determine an effective interest rate for present valuing the cash proceeds. For the income-based approach, we use a convertible bond pricing model that includes several assumptions such as volatility and a risk-free rate. For the market-based approach, we observe the price of derivative price instruments purchased in conjunction with our convertible senior note issuances or evaluate issuances of convertible debt securities by other companies with similar credit risk ratings at the time of issuance. The amount of the equity component is then calculated by deducting the fair value of the liability component from the principal amount of the instrument. Issuance costs from the instrument are then allocated to the liability and equity components in the same proportion as the proceeds. The equity component of the cash principal proceeds and the liability component of the issuance costs represent a debt discount.

Transactions involving contemporaneous exchanges of cash between the same debtor and creditor in connection with the issuance of a new debt obligation and satisfaction of an existing debt obligation by the debtor are evaluated as a modification or an exchange transaction depending on whether the exchange is determined to have substantially different terms. We extinguished the 2023 Notes at maturity. The partial repurchase of the 2026 Notes was deemed to be a modification which we accounted for as a debt extinguishment.

Stock-Based Compensation

Stock-based compensation expense is recognized for all share-based payments made to employees, directors and non-employees based on estimated fair values. The fair value of our stock options is calculated using the Black-Scholes valuation model, which requires assumptions regarding volatility, risk-free rates, forfeiture rates and expected option life. We estimate forfeitures for expense recognition based on our historical experience. Groups of employees that have similar historical forfeiture behavior are considered separately. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense for new awards may differ materially from that recorded for existing awards and stock-based compensation for non-employees will vary as the awards are re-measured over the vesting term.

Recent Accounting Pronouncements

Please refer to Part II, Item 8, "Note 2 - Significant Accounting Policies" to our Consolidated Financial Statements in this Annual Report on Form 10-K for information regarding recent accounting pronouncements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is primarily confined to our investment securities. The primary objective of our investment activities is to preserve our capital to fund operations, and we do not enter into financial instruments for trading or speculative purposes. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in high-credit-quality securities. As of December 31, 2023, we had cash, cash equivalents and short-term investments of $171.8 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. The securities in our investment portfolio are not leveraged and are classified as held-to-maturity. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative effect on the realized value of our investment portfolio. We actively monitor changes in interest rates and, with our current portfolio of short-term investments which we intend to hold to maturity, we are not exposed to significant loss due to changes in interest rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors Omeros Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Omeros Corporation (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive income (loss), shareholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of an expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosures to which it relates.

OMIDRIA Contract Royalty Asset

Description of the Matter	As more fully described in Note 2 of the financial statements, the Company recorded a contract royalty asset in connection with its sale of OMIDRIA to Rayner Surgical, Inc. on December 23, 2021. To measure that contract royalty asset, the Company used the expected value approach, which is the discounted sum of the probability-weighted royalty payments using a range of potential outcomes, to the extent that it is probable that a significant reversal in the amount of cumulative income recognized will not occur. Auditing management's forecasts is complex and requires judgment due to the level of estimation uncertainty and the sensitivity of the asset's value to changes in assumptions. In particular, the value of the OMIDRIA contract royalty asset is sensitive to changes in significant assumptions such as forecasted royalties due from Rayner Surgical, Inc. in various scenarios and the probability-weighting of those scenarios, which are affected by expectations about future market and regulatory conditions.
How We Addressed the Matter in Our Audit	To test the measurement of the OMIDRIA contract royalty asset, we performed audit procedures that included, among others, evaluating (1) the estimated future royalties in various scenarios, and (2) management's relative weighting of those scenarios. We compared estimated future royalties to the Company's historical revenues and royalty rates in the asset purchase agreement. We evaluated the appropriateness and likelihood of occurrence of the various scenarios included in management's calculation, given the Company's experience and industry trends, and verified the clerical accuracy of the calculation. We also evaluated the Company's disclosures in the consolidated financial statements related to these matters.

/s/Ernst & Young LLP

We have served as the Company's auditor since 1998.

Seattle, Washington

April 1, 2024

OMEROS CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 7,105	$ 11,009
Short-term investments	164,743	183,909
OMIDRIA contract royalty asset, short-term	29,373	28,797
Receivables	8,096	213,221
Prepaid expense and other assets	8,581	6,300
Total current assets	217,898	443,236
OMIDRIA contract royalty asset	138,736	123,425
Right of use assets	18,631	21,762
Property and equipment, net	1,950	1,492
Restricted investments	1,054	1,054
Total assets	$ 378,269	$ 590,969
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 7,712	$ 5,989
Accrued expenses	31,868	30,551
Current portion of convertible senior notes, net	—	94,381
Current portion of OMIDRIA royalty obligation	8,576	1,152
Current portion of lease liabilities	5,160	4,310
Total current liabilities	53,316	136,383
Convertible senior notes, net	213,155	220,906
OMIDRIA royalty obligation	116,550	125,126
Lease liabilities, non-current	18,143	22,426
Other accrued liabilities - noncurrent	2,088	444
Commitments and contingencies (Note 10)		
Shareholders' equity (deficit):		
Preferred stock, par value $0.01 per share, 20,000,000 shares authorized; none issued and outstanding at December 31, 2023 and December 31, 2022	—	—
Common stock, par value $0.01 per share, 150,000,000 shares authorized at December 31, 2023 and December 31, 2022; 61,128,597 and 62,828,765 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively.	611	628
Additional paid-in capital	727,936	720,773
Accumulated deficit	(753,530)	(635,717)
Total shareholders' equity (deficit)	(24,983)	85,684
Total liabilities and shareholders' equity (deficit)	$ 378,269	$ 590,969

See accompanying Notes to Consolidated Financial Statements

OMEROS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(In thousands, except share and per share data)

	Year Ended December 31,		
	2023	**2022**	**2021**
Costs and expenses:			
Research and development	$ 114,870	$ 112,721	$ 118,775
Selling, general and administrative	49,660	50,668	54,842
Total costs and expenses	164,530	163,389	173,617
Loss from operations	(164,530)	(163,389)	(173,617)
Interest expense	(30,844)	(22,702)	(19,669)
Interest and other income	16,342	4,062	1,740
Gain on early extinguishment of convertible senior notes	4,112	—	—
Net loss from continuing operations	(174,920)	(182,029)	(191,546)
Net income from discontinued operations, net of tax	57,107	229,446	385,781
Net income (loss)	$ (117,813)	$ 47,417	$ 194,235
Basic and diluted net income (loss) per share:			
Net loss from continuing operations	$ (2.79)	$ (2.90)	$ (3.07)
Net income from discontinued operations	0.91	3.66	6.19
Net income (loss)	$ (1.88)	$ 0.76	$ 3.12
Weighted-average shares used to compute basic and diluted net income (loss) per share	62,739,227	62,737,091	62,344,100

See accompanying Notes to Consolidated Financial Statements

OMEROS CORPORATION

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)

(In thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity/(Deficit)
	Shares	Amount			
Balance at December 31, 2020	61,671,231	$ 616	$ 751,304	$ (872,672)	$ (120,752)
Issuance of common stock upon exercise of stock options	945,924	10	8,372	—	8,382
Issuance of common stock upon grant of restricted stock awards	11,700	—	91	—	91
At the market offering fees	—	—	(241)	—	(241)
Stock-based compensation	—	—	17,539	—	17,539
Cumulative effect of adopting ASU 2020-06	—	—	(70,777)	(4,697)	(75,474)
Net income	—	—	—	194,235	194,235
Balance at December 31, 2021	62,628,855	626	706,288	(683,134)	23,780
Issuance of common stock upon exercise of stock options	101,160	1	414	—	415
Issuance of common stock upon vesting of restricted stock units	98,750	1	(1)	—	—
Stock-based compensation	—	—	14,072	—	14,072
Net income	—	—	—	47,417	47,417
Balance at December 31, 2022	62,828,765	628	720,773	(635,717)	85,684
Issuance of common stock upon exercise of stock options	36,726	—	150	—	150
Issuance of common stock upon vesting of restricted stock units	67,250	1	(1)	—	—
Repurchases of common stock	(1,804,144)	(18)	(4,636)	—	(4,654)
Stock-based compensation	—	—	11,650	—	11,650
Net loss	—	—	—	(117,813)	(117,813)
Balance at December 31, 2023	61,128,597	$ 611	$ 727,936	$ (753,530)	$ (24,983)

See accompanying Notes to Consolidated Financial Statements

OMEROS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2023	**2022**	**2021**
Operating activities:			
Net income (loss)	$ (117,813)	$ 47,417	$ 194,235
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Stock-based compensation expense	11,650	14,072	17,630
Non-cash interest expense on convertible senior notes	1,853	1,830	1,696
Depreciation and amortization	920	952	1,386
Remeasurement on OMIDRIA contract royalty asset	(41,167)	(14,457)	—
Interest on OMIDRIA contract royalty asset	(15,315)	(18,634)	—
Accretion on U.S. government treasury bills, net	(8,714)	—	—
Gain on early extinguishment of convertible senior notes	(4,112)	—	—
Gain on sale of OMIDRIA, gross	—	—	(310,563)
Non-cash interest expense on future royalty obligation	—	1,695	—
Changes in operating assets and liabilities:			
Receivables	205,125	(175,066)	(34,314)
OMIDRIA contract royalty asset	40,595	65,439	—
Accounts payable and accrued expense	4,682	(10,665)	14,640
Prepaid expenses and other	(2,978)	934	5,568
Net cash provided by (used in) operating activities	74,726	(86,483)	(109,722)
Investing activities:			
Purchases of investments	(1,018,602)	(429,045)	(32,006)
Proceeds from the sale and maturities of investments	1,046,482	301,594	100,000
Purchases of property and equipment	(426)	(113)	(277)
Cash proceeds on sale of OMIDRIA	—	—	125,993
Net cash provided by (used in) investing activities	27,454	(127,564)	193,710
Financing activities:			
Payments on convertible senior notes	(99,873)	—	—
Repurchases on common stock	(4,654)	—	—
Principal payments on OMIDRIA royalty obligation	(1,152)	(417)	—
Payments on finance lease obligations	(555)	(750)	(1,823)
Proceeds upon exercise of stock options	150	415	8,383
Proceeds upon entering into OMIDRIA royalty obligation	—	125,000	—
At the market offering costs	—	—	(241)
Net cash provided by (used in) financing activities	(106,084)	124,248	6,319
Net increase (decrease) in cash and cash equivalents	(3,904)	(89,799)	90,307
Cash and cash equivalents at beginning of period	11,009	100,808	10,501
Cash and cash equivalents at end of period	$ 7,105	$ 11,009	$ 100,808
Supplemental cash flow information			
Cash paid for interest	$ 29,923	$ 19,178	$ 17,876
Equipment acquired under finance lease	$ 952	$ 40	$ 289

See accompanying Notes to Consolidated Financial Statements

Note 1—Organization and Basis of Presentation

General

Omeros Corporation (“Omeros,” the “Company” or “we”) is a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting immunologic disorders including complement-mediated diseases, cancers, and addictive and compulsive disorders. We marketed our first drug product OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% for use during cataract surgery or intraocular lens replacement in the United States (the “U.S.”) until we sold OMIDRIA and related business assets on December 23, 2021 (see “Sale of OMIDRIA Assets” below for additional information).

Our pipeline of clinical-stage development programs includes: narsoplimab, our antibody targeting mannan-binding lectin-associated serine protease 2 ("MASP-2"), the effector enzyme of the lectin pathway of complement; OMS1029, our long-acting antibody targeting MASP-2; OMS906, our antibody targeting mannan-binding lectin-associated serine protease-3 ("MASP-3"), the key activator of the alternative pathway of complement; and OMS527, our phosphodiesterase 7 ("PDE7") inhibitor program.

Clinical development of narsoplimab is currently focused primarily on hematopoietic stem cell transplant-associated thrombotic microangiopathy ("TA-TMA"). Our Biologics License Application ("BLA") for narsoplimab in TA-TMA is anticipated to be resubmitted with additional information to support potential approval of narsoplimab in this indication. In October 2023, we announced the results of a pre-specified interim analysis of our Phase 3 ARTEMIS-IGAN trial evaluating narsoplimab for the treatment of immunoglobulin A ("IgA") nephropathy. Topline results showed that narsoplimab did not reach statistically significant improvement over placebo on the primary endpoint of reduction in proteinuria. Based on this result, we have discontinued the ARTEMIS-IGAN clinical trial.

Phase 1 and Phase 2 clinical programs are underway in our other clinical-stage assets.

Sale of OMIDRIA Assets

On December 23, 2021, we closed on an Asset Purchase Agreement (the “Asset Purchase Agreement”) with Rayner Surgical Inc. (“Rayner”) for the sale of our commercial product OMIDRIA. Rayner paid us $126.0 million in cash at closing, and we retained all outstanding accounts receivable, accounts payable and accrued expenses as of the closing date. Additionally, we are entitled to future royalty payments on net sales of OMIDRIA.

Under the Asset Purchase Agreement, Omeros is entitled to receive a milestone payment of $200.0 million (the “Milestone Payment”) following an event (the "Milestone Event") that establishes separate payment for OMIDRIA for a continuous period of at least four years when furnished in the ambulatory surgery center (“ASC”) setting. In December 2022, the Milestone Event occurred and we recorded a $200.0 million milestone receivable. We received the Milestone Payment in February 2023.

As a result of the divestiture, the results of OMIDRIA operations (e.g., revenues and operating costs) have been reclassified to discontinued operations in our consolidated statements of operations and comprehensive income (loss) and excluded from continuing operations for all periods presented (See “Note 7 – Discontinued Operations – Sale of OMIDRIA ”).

Basis of Presentation

Our consolidated financial statements include the financial position and results of operations of Omeros and our wholly owned subsidiaries. All inter-company transactions have been eliminated. The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”).

Liquidity and Capital Resources

As of December 31, 2023, we had cash, cash equivalents and short-term investments of $171.8 million. Our cash provided by operations for the year ended December 31, 2023 was $74.7 million and included our 2023 net loss for the year of $117.8 million and collection of the $200.0 million Milestone Payment in the first quarter of 2023. We extinguished $95.0 million outstanding of convertible senior notes at maturity in November 2023. In February 2024, we received $115.5 million upon the sale to DRI Healthcare Acquisition LP ("DRI") of substantially all of our expected remaining U.S.-only Rayner OMIDRIA royalty receipts payable through December 31, 2031 (see “Note 8 - OMIDRIA Royalty Obligation”).

Historically, we have incurred net losses from continuing operations and negative operating cash flows. We have not yet established an ongoing source of revenue sufficient to cover our operating costs; therefore, we potentially need to continue to raise additional capital to accomplish our business plan and to retire our outstanding convertible senior notes due in 2026. We plan to continue to fund our operations for at least the next twelve months with our existing cash and investments and the $115.5 million we received in February 2024 from DRI. We have a sales agreement to sell shares of our common stock, from time to time, in an "at the market" equity offering facility through which we may offer and sell shares of our common stock equaling an aggregate amount up to $150.0 million. Should it be determined to be strategically advantageous, we could pursue debt financings as well as public and private offerings of our equity securities, similar to those we have previously completed, or other strategic transactions, which may include licensing a portion of our existing technology. Should it be necessary to manage our operating expenses, we could also reduce our projected cash requirements by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

Segments

We operate in one segment. Management uses cash flow as the primary measure to manage our business and does not segment our business for internal reporting or decision-making.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant items subject to such estimates include OMIDRIA contract royalty asset valuation, stock-based compensation expense, and accruals for clinical trials and manufacturing of drug product. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from these estimates.

Note 2—Significant Accounting Policies

Discontinued Operations

We review the presentation of planned or completed business dispositions in the consolidated financial statements based on the available information and events that have occurred. The review consists of evaluating whether the business meets the definition of a component for which the operations and cash flows are clearly distinguishable from the other components of the business and, if so, whether it is anticipated that after the disposal the cash flows of the component would be eliminated from continuing operations and whether the disposition represents a strategic shift that has a major effect on operations and financial results.

Planned or completed business dispositions are presented as discontinued operations when all the criteria described above are met. For those divestitures that qualify as discontinued operations, all comparative periods presented are reclassified in the consolidated balance sheets. Additionally, the results of operations of a discontinued operation are reclassified to income from discontinued operations, net of tax, for all periods presented in the consolidated statements of operations and comprehensive income (loss). Results of discontinued operations include all revenues and expenses directly derived from such businesses. General corporate overhead is not allocated to discontinued operations. The OMIDRIA asset sale to Rayner qualifies as a discontinued operation and has been presented as such for all reporting periods presented. The Company included information regarding cash flows from discontinued operations (see "Note 7 – Discontinued Operations – Sale of OMIDRIA").

OMIDRIA Royalties, Milestones and Contract Royalty Assets

We have rights to receive future royalties from Rayner on OMIDRIA net sales at royalty rates that vary based on geography and certain regulatory contingencies. Therefore, future OMIDRIA royalties are treated as variable consideration. The sale of OMIDRIA qualified as an asset sale under GAAP. To measure the OMIDRIA contract royalty asset, we used the expected value approach which is the sum of the discounted probability-weighted royalty payments, we would receive using a range of potential outcomes, to the extent that it is probable that a significant reversal in the amount of cumulative income recognized will not occur. As contemplated by the Asset Purchase Agreement, the royalty rate applicable to U.S. net sales of OMIDRIA was reduced from 50% to 30% upon the occurrence, in December 2022, of the event triggering the $200.0 million Milestone Payment. The reduction in our royalty rate to 30% continues until the expiration or termination of the last issued and unexpired U.S. patent, which we expect to occur no earlier than 2035. Consequently, we revalued the OMIDRIA contract royalty asset using the 30% royalty rate on U.S. net sales and adjusted the probability weighted outcomes to reflect the occurrence of the Milestone Event. Royalties earned are recorded as a reduction to the OMIDRIA contract royalty asset. The amount recorded in discontinued operations in future periods will reflect interest earned on the outstanding OMIDRIA contract royalty asset at 11.0% and any amounts we receive that are different from the expected royalties. The OMIDRIA contract royalty asset is re-measured periodically using the expected value approach based on actual results and future expectations. Any required adjustment to the OMIDRIA contract royalty asset is recorded in discontinued operations.

OMIDRIA Royalty Obligation

On September 30, 2022, we sold to DRI an interest in a portion of our future OMIDRIA royalty receipts for a purchase price of $125.0 million and recorded as an "OMIDRIA royalty obligation" on our consolidated balance sheet. The liability is amortized over the term of the arrangement using the implied effective interest rate of 9.4%. Interest expense is recorded as a component of continuing operations.

To the extent our estimates of future royalties are less than previous estimates, we will adjust the carrying amount of the OMIDRIA royalty obligation to the present value of the revised estimated cash flows, discounted at the effective interest rate utilizing the cumulative catch-up method. The adjustment would be recognized as a component of net income (loss) from continuing operations (see "Note 8 - OMIDRIA Royalty Obligation").

Cash and Cash Equivalents, Short-Term Investments and Restricted Investments

Cash and cash equivalents include highly liquid investments with a maturity of three months or less on the date of purchase which can be easily converted into cash without a significant impact to their value. Short-term investment securities are classified as held-to-maturity. Investments classified as held-to-maturity are carried at cost. Amortization, accretion, interest, and dividends, realized gains and losses and declines in value judged to be other-than-temporary are included in other income. The cost of securities sold is based on the specific-identification method. Investments with maturities of less than one year, or those for which management intends to use the investments to fund current operations, are included in current assets. We evaluate whether an investment is other-than-temporarily impaired based on the specific facts and circumstances. Factors that are considered in determining whether an other-than-temporary decline in value has occurred include: the market value of the security in relation to its cost basis; the financial condition of the investee; and the intent and ability to retain the investment for a sufficient period of time to allow for recovery in the market value of the investment. Restricted investments held in money-market funds include security deposits held by our landlord.

Investment income, which is included as a component of other income, consists primarily of interest earned.

Inventory

We expense inventory costs related to product candidates as research and development expenses until regulatory approval is reasonably assured in the U.S. or the European Union ("EU"). Once approval is reasonably assured, costs, including amounts related to third-party manufacturing, transportation and internal labor and overhead, will be capitalized.

Receivables

Receivables at December 31, 2023 primarily consist of royalties receivable from Rayner. Receivables at December 31, 2022 also included the $200.0 million Milestone Payment which we received in February 2023. Considering the nature of our receivables, we concluded an allowance for doubtful accounts was not necessary as of December 31, 2023 and 2022, respectively.

Property and Equipment, Net

Property and equipment are stated at cost, and depreciation is calculated using the straight-line method over the estimated useful life of the assets, which is generally three to 10 years. Equipment acquired through finance leases is recorded as property and equipment and is amortized over the shorter of the useful lives of the related assets or the lease term. Expenditures for repairs and maintenance are expensed as incurred.

Convertible Senior Notes

On January 1, 2021, we adopted Accounting Standards Update ("ASU") 2020-06, *Debt—Debt with Conversion Options* (Subtopic 470.20 *and Derivatives and Hedging—Contracts in Entity's Own Equity* (Subtopic 815-40) on a modified retrospective basis. ASU 2020-06 removed the separate liability and equity accounting for our convertible senior notes that was required under previous guidance and allows us to account for our convertible senior notes wholly as debt. Upon adoption, we removed the equity component allocated to debt issuance costs.

Transactions involving contemporaneous exchanges of cash between the same debtor and creditor in connection with the issuance of a new debt obligation and satisfaction of an existing debt obligation are evaluated as a modification or an extinguishment depending on whether the exchange is determined to have substantially different terms. We extinguished the 6.25% convertible senior notes (the "2023 Notes") at par upon maturity on November 15, 2023. In December 2023, we repurchased $9.1 million par value of our 5.25% convertible senior notes ("2026 Notes") at a discount, realizing a $4.1 million non-cash gain on extinguishment.

Impairment of Long-Lived Assets

We assess the impairment of long-lived assets, whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of these assets is measured by comparing the carrying value to future undiscounted cash flows that the asset is expected to generate. If the asset is impaired, the amount of any impairment will be reflected in the results of operations in the period of impairment. We have not recognized any impairment losses for the years ended December 31, 2023, 2022 and 2021.

Revenue Recognition

When we enter into a customer contract, we perform the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation.

Prior to the sale of OMIDRIA to Rayner, we recorded product sales as revenue when the product was delivered to our wholesalers and title for the product was transferred. Product sales were recorded net of wholesaler distribution fees and estimated chargebacks, rebates, returns and purchase-volume discounts.

Research and Development

Research and development expenses are comprised primarily of contracted research, clinical trial study and manufacturing costs prior to approval; consulting services; contract milestones; materials and supplies; costs for personnel, including salaries, benefits and stock compensation; depreciation; an allocation of our occupancy costs; and other expenses incurred to sustain our overall research and development programs. Advance payments for goods or services that will be used for future research and development activities are deferred and then recognized as an expense as the related goods are delivered or the services are performed. All other research and development costs are expensed as incurred.

Selling, General and Administrative

Selling, general and administrative expenses are comprised primarily of marketing and selling expenses; professional and legal services; patent costs; and salaries, benefits, and stock-compensation costs for sales, marketing, and other personnel not directly engaged in research and development. Additionally, selling, general and administrative expenses include depreciation; an allocation of our occupancy costs; and other general corporate expenses. Advertising costs are expensed as incurred. We had no advertising costs during the years ended December 31, 2023 and 2022. For the year ended December 31, 2021, we incurred $0.8 million in advertising costs related to our sales of OMIDRIA.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. We recognize the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination. A valuation allowance is established when it is more likely than not that the deferred tax assets will not be realized.

Stock-Based Compensation

Stock-based compensation expense is recognized for all share-based payments, including grants of stock option awards and restricted stock units (“RSU”) based on estimated fair values. The fair value of our stock is calculated using the Black-Scholes option-pricing model, which requires judgmental assumptions around volatility, forfeiture rates, risk-free rate and expected term. Compensation expense is recognized over the requisite service periods, which is generally the vesting period, using the straight-line method. Forfeiture expense is estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates.

Common Stock Repurchases

We may repurchase shares of our common stock from time to time under authorization made by our Board of Directors. Under applicable Washington State law, repurchased shares are retired and not presented separately as treasury stock on the consolidated financial statements.

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) is comprised of net income (loss) and certain changes in equity that are excluded from net income (loss). There was no difference between comprehensive income (loss) and net income (loss) for the years ended December 31, 2023, 2022 and 2021.

Financial Instruments and Concentrations of Credit Risk

Cash and cash equivalents, receivables, accounts payable and accrued liabilities, which are recorded at invoiced amount or cost, approximate fair value based on the short-term nature of these financial instruments. The fair value of short-term investments is based on quoted market prices. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments and receivables. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, our cash and cash equivalents balance held at a financial institution may exceeds the federally insured limits. To limit the credit risk, we invest our excess cash in high-quality securities such as money market mutual funds, certificates of deposit and U.S. treasury bills.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board issued ASU 2023-09, *Income Taxes - Improvements to Income Tax Disclosure* (Topic 740), to enhance the transparency of income tax disclosures. ASU 2023-09 provides enhancements to the income tax disclosures related to the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for fiscal years after December 15, 2025 and applied prospectively. The Company is evaluating the impact of this pronouncement on its consolidated financial statements.

Note 3—Net Income (Loss) Per Share

Basic net income (loss) per share ("Basic EPS") is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share ("Diluted EPS") is computed by dividing net income (loss) by the weighted average number of common shares and potentially dilutive common shares outstanding during the period. Our potentially dilutive securities include common shares related to our stock options, RSUs and convertible senior notes calculated using the treasury stock method. In periods where we have a net loss from continuing operations but overall net income, we do not compute Diluted EPS. Potentially dilutive securities excluded from Diluted EPS are as follows:

	Year Ended December 31,		
	2023	2022	2021
2026 Notes convertible to common stock (1)	11,132,366	12,172,008	12,172,008
2023 Notes convertible to common stock (1)(2)	4,318,944	4,941,739	4,941,739
Outstanding options to purchase common stock	38,462	9,488	1,707,371
Outstanding restricted stock units	—	98,750	2,642
Total dilutive shares excluded from net income (loss) per share	15,489,772	17,221,985	18,823,760

(1) The 2023 Notes were, and the 2026 Notes are subject to a capped call arrangement that potentially reduces the dilutive effect as described in "Note 6 - Convertible Senior Notes". Any potential impact of the capped call arrangement is excluded from this table.

(2) The 2023 Notes were fully extinguished on November 15, 2023.

Note 4—Fair-Value Measurements

All of our investments are held in our name and are classified as short-term and held-to-maturity. Interest income from investments for the years ended December 31, 2023 and December 31, 2022 were $14.7 million and $2.2 million, respectively.

The following tables summarize our investments:

	December 31, 2023		
	Amortized Cost	Gross Unrealized Gains/(Losses)	Estimated Fair Value
		(In thousands)	
U.S. government securities classified as short-term investments	$ 102,100	$ 19	$ 102,119
Money-market funds classified as short-term investments	62,643	—	62,643
Total short-term investments	164,743	19	164,762
Certificate of deposit classified as non-current restricted investments	1,054	—	1,054
Total investments	$ 165,797	$ 19	$ 165,816

	December 31, 2022		
	Amortized Cost	Gross Unrealized Gains/(Losses)	Estimated Fair Value
		(In thousands)	
U.S. government securities classified as short-term investments	$ 99,027	$ 22	$ 99,049
Money-market funds classified as short-term investments	84,882	—	84,882
Total short-term investments	183,909	22	183,931
Certificate of deposit classified as non-current restricted investments	1,054	—	1,054
Total investments	$ 184,963	$ 22	$ 184,985

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The accounting standard establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available. The following summarizes the three levels of inputs required:

Level 1—Observable inputs for identical assets or liabilities, such as quoted prices in active markets;

Level 2—Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3—Unobservable inputs in which little or no market data exists, therefore they are developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

Our fair-value hierarchy for our financial assets are as follows:

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
U.S. government securities classified as short-term investments	$ —	$ 102,119	$ —	$ 102,119
Money-market funds classified as short-term investments	62,643	—	—	62,643
Total short-term investments	62,643	102,119	—	164,762
Money-market funds classified as non-current restricted investments	1,054	—	—	1,054
Total investments	$ 63,697	$ 102,119	$ —	$ 165,816

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
U.S. government treasury bills classified as short-term investments	$ —	$ 99,049	$ —	$ 99,049
Money-market funds classified as short-term investments	84,882	—	—	84,882
Total short-term investments	84,882	99,049	—	183,931
Money-market funds classified as non-current restricted investments	1,054	—	—	1,054
Total investments	$ 85,936	$ 99,049	$ —	$ 184,985

Unrealized gains and losses on our short-term investments were not material for either period presented. Cash held in demand deposit accounts of $7.1 million and $11.0 million is excluded from our fair-value hierarchy disclosure as of December 31, 2023 and 2022, respectively. The carrying amounts for receivables, accounts payable and accrued liabilities, and other current monetary assets and liabilities, including lease financing obligations, approximate fair value.

See “Note 6 - Convertible Senior Notes” and “Note 8 – OMIDRIA Royalty Obligation” for the carrying amount and estimated fair value of our 2023 Notes, 2026 Notes and the OMIDRIA royalty obligation.

Note 5—Certain Balance Sheet Accounts

Receivables

Receivables consists of the following:

	December 31, 2023	December 31, 2022
	(In thousands)	
OMIDRIA milestone receivable	$ —	$ 200,000
OMIDRIA royalty receivables	6,724	12,966
Other receivables	1,372	255
Total receivables	$ 8,096	$ 213,221

Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31, 2023	December 31, 2022
	(In thousands)	
Equipment under finance leases	$ 6,929	$ 6,204
Laboratory equipment	3,525	3,135
Computer equipment	1,113	1,076
Office equipment and furniture	624	625
Total cost	12,191	11,040
Less accumulated depreciation and amortization	(10,241)	(9,548)
Total property and equipment, net	$ 1,950	$ 1,492

For the years ended December 31, 2023, 2022 and 2021, depreciation and amortization expenses were $0.9 million, $1.0 million and $1.4 million, respectively.

Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2023	December 31, 2022
	(In thousands)	
Clinical trials	$ 10,168	$ 5,536
Employee compensation	7,380	6,665
Contract research and development	6,223	3,209
Interest payable	4,242	5,172
Consulting and professional fees	3,539	4,425
Other accrued expenses	316	5,544
Total accrued expenses	$ 31,868	$ 30,551

Note 6—Convertible Senior Notes

On January 1, 2021, we adopted ASU 2020-06, *Debt—Debt with Conversion Options* (Subtopic 470-20) *and Derivatives and Hedging—Contracts in Entity's Own Equity* (Subtopic 815-40) on a modified retrospective basis. ASU 2020-06 removes the separate liability and equity accounting for our convertible senior notes. Consequently, we now account for our convertible senior notes wholly as debt. Upon adoption, we removed the equity component allocated to debt issuance costs increasing convertible senior notes and shareholders' equity by $75.5 million.

In December 2023, we repurchased $9.1 million par value of our 2026 Notes realizing a non-cash gain on debt extinguishment of $4.1 million to our consolidated statement of operations and comprehensive loss in the current year. On November 15, 2023, we also extinguished at par the $95.0 million outstanding principal amount on our 2023 Notes.

Convertible senior notes outstanding at December 31, 2023 and 2022, respectively, are as follows:

	Balance as of December 31, 2023		
	2023 Notes	2026 Notes	Total
		(In thousands)	
Principal amount	$ —	$ 215,924	$ 215,924
Unamortized debt issuance costs	—	(2,769)	(2,769)
Total convertible senior notes, net	$ —	$ 213,155	$ 213,155
Fair value of outstanding convertible senior notes (1)	$ —	$ 131,444	

	Balance as of December 31, 2022		
	2023 Notes	2026 Notes	Total
		(In thousands)	
Principal amount	$ 95,000	$ 225,030	$ 320,030
Unamortized debt issuance costs	(619)	(4,124)	(4,743)
Total convertible senior notes, net	$ 94,381	$ 220,906	$ 315,287
Fair value of outstanding convertible senior notes (1)	$ 92,031	$ 118,141	

(1) The fair value is classified as Level 3 due to the limited trading activity for the convertible senior notes.

2023 Convertible Senior Notes

The 2023 Notes accrued interest at an annual rate of 6.25% per annum. The 2023 Notes matured on November 15, 2023, and the $95.0 million outstanding principal and related accrued interest were paid at that time.

The following table sets forth total interest expense recognized in connection with the 2023 Notes:

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Contractual interest expense	$ 5,195	$ 5,938	$ 5,938
Amortization of debt issuance costs	619	663	618
Total interest expense	$ 5,814	$ 6,601	$ 6,556

2026 Convertible Senior Notes

The 2026 Notes are unsecured and accrue interest at an annual rate of 5.25% per annum, payable semi-annually in arrears on February 15 and August 15 of each year. The 2026 Notes mature on February 15, 2026, unless earlier purchased, redeemed or converted in accordance with their terms.

The initial conversion rate is 54.0906 shares of our common stock per $1,000 of note principal (equivalent to an initial conversion price of approximately $18.4875 per share of common stock), which equals approximately 12.2 million shares issuable upon conversion, subject to adjustment in certain circumstances.

The 2026 Notes are convertible at the option of the holders on or after November 15, 2025 at any time prior to the close of business on February 12, 2026, the second scheduled trading day immediately before the stated maturity date of February 15, 2026. Additionally, holders may convert their 2026 Notes at their option at specified times prior to the maturity date only if:

(1) during any calendar quarter, beginning after September 30, 2020, that the last reported sale price per share of our common stock exceeds 130% of the conversion price of the 2026 Notes for each of at least 20 trading days in the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;

(2) during the five consecutive business days immediately after any five-consecutive-trading-day period (such five-consecutive-trading-day period, the "measurement period") in which the trading price per $1,000 principal amount of 2026 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of our common stock on such trading day and the conversion rate on such trading day;

(3) there is an occurrence of one or more certain corporate events or distributions of our common stock; or

(4) we call the 2026 Notes for redemption.

We will settle any conversions by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election, based on the applicable conversion rate(s).

Subject to the satisfaction of certain conditions, we may redeem in whole or in part the 2026 Notes at our option beginning August 15, 2023 through the 50th scheduled trading day immediately before the maturity date at a cash redemption price equal to the principal amount of the 2026 Notes to be redeemed plus any accrued and unpaid interest to, but excluding, the redemption date. The 2026 Notes are subject to redemption only if certain requirements are satisfied, including that the last reported sale price per share of our common stock exceeds 130% of the conversion price on (i) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date we send the related redemption notice and (ii) the trading day immediately before the date we send such notice.

In order to reduce the dilutive impact or potential cash expenditure associated with the conversion of the 2026 Notes, we entered into capped call transactions in connection with the issuances of the 2026 Notes (the "2026 Capped Call"). The 2026 Capped Call will cover, subject to anti-dilution adjustments substantially similar to those applicable to the 2026 Notes, the number of shares of common stock underlying the 2026 Notes when our common stock is trading within the range of approximately $18.49 and $26.10. However, should the market price of our common stock exceed the $26.10 cap, then the conversion of the 2026 Notes would have an additional dilutive impact or may require a cash expenditure to the extent the market price exceeds the cap price. The 2026 Capped Call will expire on various dates over the 50-trading-day period ranging from December 2, 2025 to February 12, 2026, if not exercised earlier. The 2026 Capped Call is a separate transaction and not part of the terms of the 2026 Notes and was executed separately from the issuance of the 2026 Notes. The amount paid for the 2026 Capped Call was recorded as a reduction to additional paid-in capital in the consolidated balance sheet. As of December 31, 2023, approximately 12.2 million shares remained outstanding under the 2026 Capped Call.

Further, we concluded the 2026 Capped Call qualifies for a derivative scope exception for instruments that are both indexed to an entity's own stock and classified in stockholders' equity in its balance sheet. Consequently, the fair value of the 2026 Capped Call of $23.2 million is classified as equity, not accounted for as derivatives, and will not be subsequently remeasured.

The unamortized debt issuance costs of $2.8 million as of December 31, 2023 will be amortized to interest expense at an effective interest rate of 5.9% over the remaining term.

The following table sets forth interest expense recognized related to the 2026 Notes:

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Contractual interest expense	$ 11,774	$ 11,814	$ 11,814
Amortization of debt issuance costs	1,355	1,167	1,078
Total interest expense	$ 13,129	$ 12,981	$ 12,892

Note 7—Discontinued Operations - Sale of OMIDRIA

On December 23, 2021, we closed the sale of OMIDRIA and related assets, which is reported as discontinued operations in our consolidated statements of operations and comprehensive income. Upon closing, we received an up-front cash payment from Rayner of $126.0 million, and we retained the outstanding receivables and liabilities related to OMIDRIA as of the closing date.

The year ended December 31, 2021, included a gain on the sale of OMIDRIA comprised as follows (in thousands):

Cash proceeds	$ 125,993
OMIDRIA contract royalty asset	184,570
Gain on sale of OMIDRIA, gross	310,563
Transaction and closing costs	(1,972)
RSUs granted to transferred employees	(1,419)
Prepaid assets and inventory at cost	(1,524)
Gain on sale of OMIDRIA	$ 305,648

In December 2022, the achievement of the Milestone Event triggered a $200.0 million Milestone Payment from Rayner which we received in February 2023. The Milestone Event also resulted in a reduction in the U.S. royalty rate from 50% to 30% on OMIDRIA net sales.

The results of operations for OMIDRIA are recorded as income from discontinued operations for all periods presented in the consolidated statements of operations and comprehensive income (loss).

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Product sales, net	$ —	$ —	$ 110,735
Costs and expenses	—	—	30,631
Gross margin	—	—	80,104
Gain on sale of OMIDRIA	—	—	305,648
Milestone income	—	200,000	—
Interest on OMIDRIA contract royalty asset	15,315	18,634	—
Remeasurement adjustments	41,167	14,457	—
Other income	1,087	307	1,035
Income before income tax	57,569	233,398	386,787
Income tax expense (1)	(462)	(3,952)	(1,006)
Net income from discontinued operations, net of tax	$ 57,107	$ 229,446	$ 385,781

(1) For further discussion of income tax expense refer to “Note 13 – Income Taxes”.

The following schedule is a rollforward of the OMIDRIA contract royalty asset (in thousands):

Balance at December 31, 2021	$ 184,570
Royalties earned	(65,439)
Interest on OMIDRIA contract royalty asset	18,634
Remeasurement adjustments	14,457
Balance at December 31, 2022	152,222
Royalties earned	(40,595)
Interest on OMIDRIA contract royalty asset	15,315
Remeasurement adjustments	41,167
Balance at December 31, 2023	$ 168,109

Cash flow from discontinued operations is as follows:

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Net cash provided by discontinued operations from operating activities	$ 241,317	$ 78,082	$ 55,380
Net cash provided by discontinued operations from investing activities	$ —	$ —	$ 125,993

Note 8—**OMIDRIA Royalty Obligation**

In September 2022, we sold to DRI an interest in our future OMIDRIA royalty receipts and received $125.0 million in cash consideration which was recorded as an OMIDRIA royalty obligation on our consolidated balance sheet. DRI is entitled to receive royalties on OMIDRIA net sales between September 1, 2022 and December 31, 2030, subject to annual caps. DRI receives their prorated monthly cap amount before we receive any royalty proceeds. DRI is not entitled to carry-forward nor recoup any shortfall if the royalties paid by Rayner for an annual period are less than the cap amount applicable to each discrete calendar year. Additionally, DRI has no recourse to or security interest in our assets other than our OMIDRIA royalty receipts.

The changes in the OMIDRIA royalty obligation during the year ended December 31, 2023 are as follows (in thousands):

Balance at December 31, 2022	$ 126,278
Principal payments	(1,152)
Balance at December 31, 2023	$ 125,126

The OMIDRIA royalty obligation is classified as a Level 3 liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market. As of December 31, 2023, the approximate fair value of our obligation was $116.3 million.

For the years ended December 31, 2023 and December 31, 2022, we incurred interest expense of $11.8 million and $2.9 million, respectively, on the OMIDRIA royalty obligation.

As of December 31, 2023, the maximum scheduled principal and interest payments (based on an implied effective interest rate of 9.4%) are as follows:

	Principal	Interest	Total Annual Cap
		(In thousands)	
2024	$ 8,576	$ 11,424	$ 20,000
2025	14,641	10,359	25,000
2026	16,081	8,919	25,000
2027	17,664	7,336	25,000
2028	19,402	5,598	25,000
Thereafter	48,762	4,988	53,750
Total scheduled payments	$ 125,126	$ 48,624	$ 173,750

Subsequent Event

In February 2024, Omeros and DRI expanded their royalty purchase agreement, resulting in Omeros receiving $115.5 million in cash consideration from DRI upon closing. The Amended and Restated Royalty Purchase Agreement ("RPA") eliminated the caps on royalty payments effective in the first quarter of 2024 and provides that DRI will now receive all royalties on U.S. net sales of OMIDRIA payable between January 1, 2024 and December 31, 2031. DRI is entitled to payment only to the extent of royalty payments that are payable in the respect of U.S. net sales of OMIDRIA on or before December 31, 2031 and DRI has no recourse to our assets other than its interest in OMIDRIA royalties. Omeros retains the right to receive all royalties payable by Rayner on any net sales of OMIDRIA outside the U.S. payable from and after January 1, 2024, as well as royalties on global net sales of OMIDRIA payable from and after December 31, 2031. To date, international royalties have not been significant. We are also entitled to receive a milestone ranging between $10.0 million and $27.5 million if U.S. net sales of OMIDRIA reach applicable thresholds ranging between a total of $156.0 million and $160.0 million for any period of four consecutive quarters prior to January 1, 2026. In addition, we are entitled to receive a separate milestone ranging between $8.0 million and $27.5 million if U.S. net sales of OMIDRIA reach applicable thresholds ranging between a total of $181.0 million and $185.0 million for any period of four consecutive quarters prior to January 1, 2028.

Note 9—Lease Liabilities

We have operating leases related to our office and laboratory space. The initial term of the leases is through November 2027 and we have two options to extend the lease term, each by five years. We have finance leases for certain laboratory and office equipment that have lease terms expiring through November 2026.

Lease-related assets and liabilities recorded on our consolidated balance sheet are as follows:

	December 31, 2023	December 31, 2022
	(In thousands)	
Assets		
Operating lease assets	$ 18,631	$ 21,762
Finance lease assets, net	1,220	945
Total lease assets	$ 19,851	$ 22,707
Liabilities		
Current:		
Operating leases	$ 4,590	$ 3,888
Finance leases	570	422
Non-current:		
Operating leases	17,424	21,971
Finance leases	719	455
Total lease liabilities	$ 23,303	$ 26,736
Weighted-average remaining lease term		
Operating leases (years)	3.8	4.8
Finance leases (years)	2.3	2.3
Weighted-average discount rate		
Operating leases	12.81%	12.81%
Finance leases	8.57%	10.44%

The components of total lease costs are as follows:

	Year Ended December 31,	
	2023	2022
	(In thousands)	
Lease cost		
Operating lease cost	$ 6,464	$ 6,152
Finance lease cost:		
Amortization	677	812
Interest	174	174
Variable lease cost	3,160	3,191
Sublease income	(1,500)	(1,755)
Net lease cost	$ 8,975	$ 8,574

The supplemental cash flow information related to leases is as follows:

	Year Ended December 31,	
	2023	2022
	(In thousands)	
Cash paid for amounts included in the measurement of lease liabilities		
Cash payments for operating leases	$ 7,144	$ 7,072
Cash payments for financing leases	$ 655	$ 790

The future maturities of our lease liabilities as of December 31, 2023 are as follows:

	Operating Leases	Finance Leases	Total
		(In thousands)	
2024	$ 8,528	$ 684	$ 9,212
2025	7,088	517	7,605
2026	6,870	258	7,128
2027	5,950	—	5,950
Total undiscounted lease payments	28,436	1,459	29,895
Less interest	(6,422)	(170)	(6,592)
Total lease liabilities	$ 22,014	$ 1,289	$ 23,303

Note 10—Commitments and Contingencies

Contracts

We have various agreements with third parties that collectively require payment of termination fees totaling $25.8 million as of December 31, 2023 if we cancel the work within specific time frames, either prior to commencing or during performance of the contracted services.

Development Milestones and Product Royalties

We have entered a variety of development, collaboration, licensing or similar agreements with third parties under which we have accessed technology or services in connection with our development assets and programs. Some of these agreements require milestone payments based on achievements of development, regulatory or sales milestones, and/or low-single to low-double digit royalties on net income or net sales of the relevant product. For the years ended December 31, 2023, 2022 and 2021, we paid $5.0 million, $0.3 million and $0.5 million, respectively in development milestones.

Note 11—Shareholders' Equity (Deficit)

Common Stock

As of December 31, 2023, we had reserved shares of common stock under our equity plans as follows:

Stock options outstanding	15,255,154
Awards available to issue under the 2017 Plan	8,802,249
Total shares reserved	24,057,403

At the Market Sales Agreement – We have a sales agreement to sell shares of our common stock having an aggregate offering price of up to $150.0 million, from time to time, through an "at the market" equity offering program.

Amendment of 2017 Omnibus Incentive Compensation Plan - At our June 23, 2023 annual meeting, our shareholders approved a 5,000,000 share increase in the number of shares of common stock available for grant under the 2017 Omnibus Incentive Compensation Plan, as amended and restated.

Share Repurchase Program - On November 9, 2023, the Board of Directors approved an indefinite-term share repurchase program under which we may repurchase from time to time up to $50.0 million of our common stock in the open market or through privately negotiated transactions. For the year ended December 31, 2023, we repurchased and retired 1.8 million shares of common stock at an average share price of $2.54, for an aggregate repurchase price of $4.7 million.

Note 12—Stock-Based Compensation

Our equity plans provide for the grant of incentive and non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, performance units, performance shares and other stock and cash awards to employees and consultants. Stock options are granted with an exercise price not less than the fair market value of Omeros' common stock on the date of the grant. Any unexercised options expire 10 years from grant date, and any unvested stock options granted which are subsequently canceled become available for future reissuance.

Vesting schedules for our equity plans generally are as follows:

Grant Type	Vesting Schedule
Employee initial options grants	25% at one-year anniversary, 1/48 monthly thereafter
Employee recurring options grants	1/48 monthly
Non-employee consultant options grants	1/12 or 1/48 monthly
Employee RSUs	50% after one year, 50% after two years

Stock-based compensation expense is as follows:

	Year Ended December 31,		
	2023	2022	2021
		(In thousands)	
Continuing operations:			
Research and development	$ 4,754	$ 6,123	$ 6,791
Selling, general and administrative	7,140	8,042	8,154
Total stock-based compensation in continuing operations	11,894	14,165	14,945
Discontinued operations	(244)	(93)	2,685
Total stock-based compensation	$ 11,650	$ 14,072	$ 17,630

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were applied to stock option grants during the periods ended:

	Year Ended December 31,		
	2023	2022	2021
Estimated weighted-average fair value	$ 2.44	$ 2.94	$ 10.54
Weighted-average assumptions:			
Expected volatility	93%	90%	81%
Expected life, in years	7.2	6.0	6.0
Risk-free interest rate	3.97%	2.83%	1.06%
Expected dividend yield	—%	—%	—%

Expected volatility is based on the historical volatility of our stock price weighted by grant issuances over the reporting period. We estimated the expected life of the stock options granted using the historical exercise behavior of option holders. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Forfeiture expense is estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates.

Stock option activity for all stock option plans is as follows:

	Options Outstanding	Weighted-Average Exercise Price per Share	Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2022	13,872,973	$ 11.02		
Granted	3,153,200	3.01		
Exercised	(36,726)	4.10		
Forfeited	(1,734,293)	9.96		
Balance at December 31, 2023	15,255,154	$ 9.50	6.2	$ 1,388
Vested and expected to vest at December 31, 2023	14,762,090	$ 9.65	6.0	$ 1,272
Exercisable at December 31, 2023	10,554,140	$ 11.50	4.7	$ 217

Of the 15.3 million common stock options outstanding as of December 31, 2023, 12.3 million have an exercise price above the $3.27 closing price of our stock on the Nasdaq exchange on December 31, 2023. The total intrinsic value of stock options exercised during the years ended December 31, 2023, 2022 and 2021 was $0.1 million, $0.2 million and $7.8 million, respectively.

At December 31, 2023, there were 4.7 million unvested stock options outstanding that vest over a weighted-average period of 2.1 years. The remaining estimated compensation expense to be recognized in connection with these unvested stock options is $14.5 million.

RSU activity for all stock plans is as follows:

	RSUs Outstanding	Weighted- Average Grant Date Fair Value Per Share
Balance at December 31, 2022	98,750	$ 7.53
Vested and released	(67,250)	7.53
Forfeited	(31,500)	7.53
Balance at December 31, 2023	—	$ —

Note 13—Income Taxes

The components of income tax benefit from continuing and discontinued operations were as follows:

	December 31,		
	2023	2022	2021
		(In thousands)	
Continuing operations:			
Current income tax expense:			
Federal	$ —	$ —	$ —
State	—	—	—
Total current income tax expense	—	—	—
Deferred income tax benefit:			
Federal	—	—	—
State	—	—	—
Total deferred income tax benefit	—	—	—
Income tax benefit in continuing operations	$ —	$ —	$ —
Income tax expense as a component of discontinued operations	$ 462	$ 3,952	$ 1,006

For the years ended December 31, 2023, 2022 and 2021, for federal and state income tax purposes, we had net losses from continuing operations and net income from discontinued operations, which resulted in an overall tax loss. At December 31, 2023, 2022 and 2021, we had federal net operating loss ("NOL") carryforwards of approximately $398.6 million, $361.4 million and $630.6 million, respectively, for all periods. At December 31, 2023, 2022 and 2021, we had state NOL carryforwards of approximately $245.8 million, $226.3 million and $245.1 million, respectively. In 2023, we had a net loss for federal income tax purposes and in 2022 and 2021, we utilized existing net operating loss carryforwards of $268.6 million and $245.1 million, respectively to fully offset our federal tax liability for both periods. We recorded state income tax expense of $0.5 million, $4.0 million and $1.0 million in discontinued operations in 2023, 2022 and 2021, respectively as we did not have adequate net operating losses and tax credits to fully offset our state tax liability.

Deferred income tax assets and liabilities reflect the tax effect of net operating loss and tax credit carryforwards and the net temporary difference between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of deferred income taxes were as follows:

	December 31,	
	2023	2022
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 95,183	$ 85,887
Research and development tax credits	92,837	78,992
Capitalized research and development	39,318	21,864
OMIDRIA royalty obligation	28,903	28,938
Stock-based compensation	10,132	12,517
Lease liability	5,085	5,926
Other	10,283	9,234
Total deferred tax assets	281,741	243,358
Deferred tax liabilities:		
OMIDRIA contract royalty asset	(38,832)	(34,883)
Right of use assets	(4,304)	(4,987)
Property and equipment	(122)	(288)
Total deferred tax liabilities	(43,258)	(40,158)
Net deferred tax assets before valuation allowance	238,483	203,200
Less valuation allowance	(238,483)	(203,200)
Net deferred tax liabilities	$ —	$ —

As of December 31, 2023, we had federal net operating loss carryforwards of approximately $398.6 million and state net operating loss carryforwards of approximately $245.8 million. Pre-2018 federal net operating losses of $109.8 million expire between 2035 and 2037. Post-2018 federal net operating losses of $288.8 million do not expire. Research and development tax credit carryforwards of $93.0 million expire between 2024 and 2043.

The Tax Cuts and Jobs Act was enacted on December 22, 2017 and includes the requirement to capitalize and amortize research and experimental expenditures beginning in 2022. Prior to 2022, we expensed these costs as incurred for tax purposes.

Reconciliation of income tax computed at federal statutory rates to the reported provisions for income taxes from continuing operations are as follows:

	Year ended December 31,		
	2023	2022	2021
U.S. Federal statutory rate on net loss	(21.0)%	(21.0)%	(21.0)%
State tax, net of federal tax benefit	(2.1)%	(1.7)%	(0.6)%
Change in valuation allowance	27.7%	28.3%	26.9%
Tax credits	(8.0)%	(6.8)%	(5.5)%
Stock compensation	1.5%	1.4%	0.3%
Other	1.9%	(0.2)%	(0.1)%
Effective tax rate	0.0%	0.0%	0.0%

We file federal and certain state income tax returns, which provides varying statutes of limitations on assessments. However, because of net operating loss carryforwards, substantially all our tax years remain open to federal and state tax examination.

As of December 31, 2023 and 2022, the total amount of gross unrecognized tax benefits was $2.0 million and $0.2 million, respectively. We recognized $0.3 million of interest and penalties at December 31, 2023 as an unrecognized tax benefit. As of December 31, 2023, $1.8 million of the total unrecognized tax benefits, if recognized, would have an impact on our effective tax rate. We estimate that there will be no material changes in this uncertain tax position for the next 12 months. Our policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

The following table summarizes the activities related to our gross unrecognized tax benefits (in thousands):

Balance at December 31, 2022	$	212
Increase in balance related to tax positions taken during prior years		1,796
Decrease in balance related to tax positions during prior years		(30)
Decrease in balance as a result of a lapse of the applicable statute of limitations		(12)
Balance at December 31, 2023	$	1,966

Note 14—401(k) Retirement Plan

Our 401(k) retirement plan provides for an annual company discretionary match on employee contributions. For the years-ended December 31, 2023, 2022 and 2021, Omeros' 401(k) match expense was $0.6 million, $0.6 million and $0.8 million, respectively. We match up to 4.0% of each participating employee's eligible earnings, with a maximum company match of $4,000 per employee per year. All employees are eligible to participate.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2023. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our principal executive and principal financial officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management, with the participation of our principal executive and principal financial officers, conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 framework). Based on the results of this assessment and on those criteria, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during our fourth fiscal quarter of 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

(a) None.

(b) During the three months ended December 31, 2023, none of our directors or officers adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2024 Annual Meeting of Shareholders and is incorporated herein by reference. Certain information required by this item concerning executive officers is set forth in Part I of this Annual Report on Form 10-K under the heading "Business - Information About Our Executive Officers and Significant Employees."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2024 Annual Meeting of Shareholders and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

Except for the information set forth below, the information required by this item will be contained in our definitive proxy statement issued in connection with the 2024 Annual Meeting of Shareholders and is incorporated herein by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain information regarding our equity compensation plans in effect as of December 31, 2023:

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by security holders:				
2017 Omnibus Incentive Compensation Plan (1)	11,201,040	$	8.82	8,802,249
2008 Equity Incentive Plan (2)	4,054,114	$	11.37	—
Total	15,255,154	$	9.50	8,802,249

(1) Our 2017 Plan provides for the grant of incentive and non-statutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants and subsidiary corporations' employees and consultants. The 2017 Plan replaced the 2008 Plan, and as a result we will not grant any new awards under the 2008 Plan. Any stock option awards granted under the 2008 Plan that were outstanding as of the effective date of the 2017 Plan remained in effect pursuant to their terms and, if the award is canceled or is repurchased, the shares underlying such award become available for grant under the 2017 Plan.

(2) The 2008 Plan provided for the grant of incentive and non-statutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, directors and consultants and subsidiary corporations' employees and consultants.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2024 Annual Meeting of Shareholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be contained in our definitive proxy statement issued in connection with the 2024 Annual Meeting of Shareholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements

See the Index to Consolidated Financial Statements in Part II, Item 8 of this Form 10-K.

2. Financial Statement Schedules

All schedules have been omitted as the required information is either not required, not applicable or otherwise included in the Financial Statements and notes thereto.

3. Exhibits

The following list of exhibits includes exhibits submitted with this Form 10-K as filed with the SEC and those incorporated by reference to other filings.

EXHIBIT INDEX

		Incorporated by Reference				
Exhibit No.	Exhibit Description	Form	File No.	Exhibit No.	Filing Date	Filed Herewith
1.1	Sales Agreement, dated March 1, 2021, between Omeros Corporation and Cantor Fitzgerald & Co.	10-K	001-34475	1.1	03/01/2021	
3.1	Amended and Restated Articles of Incorporation of Omeros Corporation	10-K	001-34475	3.1	03/31/2010	
3.2	Amended and Restated Bylaws of Omeros Corporation	10-K	001-34475	3.2	03/31/2010	
4.1	Description of Common Stock	10-K	001-34475	4.1	03/01/2021	
4.2	Form of Omeros Corporation common stock certificate	S-1/A	333-148572	4.1	10/02/2009	

4.3	Indenture, dated as of August 14, 2020, between Omeros Corporation and Wells Fargo Bank, National Association, as trustee	8-K	001-34475	4.1	08/14/2020
4.4	First Supplemental Indenture, dated as of August 14, 2020, between Omeros Corporation and Wells Fargo Bank, National Association, as trustee (including the form of 5.25% Convertible Senior Notes due 2026)	8-K	001-34475	4.2	08/14/2020
10.1*	Form of Indemnification Agreement entered into between Omeros Corporation and its directors and officers	S-1	333-148572	10.1	01/09/2008
10.2*	2008 Equity Incentive Plan (as amended)	10-K	001-34475	10.6	03/16/2017
10.3*	Form of Stock Option Award Agreement under the 2008 Equity Incentive Plan	10-Q	001-34475	10.2	11/07/2013
10.4*	2017 Omnibus Incentive Compensation Plan (as amended and restated effective as of June 23, 2023)	8-K	001-34475	10.1	06/28/2023
10.5*	Form of Stock Option Award Agreement under the 2017 Omnibus Incentive Compensation Plan	S-8	333-218882	4.4	06/21/2017

10.6*	Second Amended and Restated Employment Agreement between Omeros Corporation and Gregory A. Demopulos, M.D. dated April 7, 2010	8-K	001-34475	10.1	04/12/2010
10.7*	Omeros Corporation Non-Employee Director Compensation Policy	10-K	001-34475	10.11	03/13/2023
10.8	Lease dated January 27, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	8-K	001-34475	10.1	02/01/2012
10.9	First Amendment to Lease dated November 5, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.2	11/09/2012
10.10	Second Amendment to Lease dated November 16, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.18	03/18/2013
10.11	Third Amendment to Lease dated October 16, 2013 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.18	03/13/2014
10.12	Fourth Amendment to Lease dated September 8, 2015 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.3	11/09/2015
10.13	Fifth Amendment to Lease dated September 1, 2016 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.1	05/10/2017
10.14	Sixth Amendment to Lease dated October 18, 2018 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.19	03/01/2019

10.15	Seventh Amendment to Lease dated April 15, 2019 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.1	08/08/2019
10.16	Eighth Amendment to Lease dated October 18, 2019 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.20	03/02/2020
10.17	Ninth Amendment to Lease dated January 15, 2020 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.1	05/11/2020
10.18	Tenth Amendment to Lease dated September 15, 2020 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.1	11/09/2020
10.19	Eleventh Amendment to Lease dated October 23, 2020 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.23	03/01/2021
10.20	Twelfth Amendment to Lease dated January 1, 2021 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.24	03/01/2021
10.21	Thirteenth Amendment to Lease dated January 1, 2021 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.1	08/09/2021
10.22	Fourteenth Amendment to Lease dated January 14, 2022 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.1	05/10/2022

10.23†	License Agreement between Omeros Corporation and Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.) dated March 3, 2010	X
10.24†	Amendment No. 1 to License Agreement with an effective date of January 5, 2011 between Omeros Corporation and Daiichi Sankyo Co., Ltd.	X
10.25†	Amendment No. 2 to License Agreement with an effective date of January 25, 2013 between Omeros Corporation and Daiichi Sankyo Co., Ltd.	X

10.26	Form of capped call transaction confirmation, in reference to the 5.25% Convertible Senior Notes due 2026	8-K	001-34475	10.1	08/14/2020	
10.27†	Master Services Agreement, dated July 28, 2019, between Omeros Corporation and Lonza Biologics Tuas Pte. Ltd.	10-Q	001-34475	10.1	11/12/2019	
10.28†	Technology License Agreement, effective August 28, 2020 between Omeros Corporation and Xencor, Inc.	10-K	001-34475	10.1	03/13/2023	
10.29†	Asset Purchase Agreement, dated as of December 1, 2021 among Omeros Corporation, Rayner Surgical Inc. and Rayner Surgical Group, Limited, as Parent Guarantor	10-K	001-34475	10.1	03/01/2022	
10.30†	Amended and Restated Royalty Purchase Agreement between Omeros Corporation and DRI Healthcare Acquisitions LP dated February 1, 2024					X
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Principal Executive Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Principal Financial Officer Pursuant to Rule 13-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
97.1	Omeros Corporation Compensation Clawback Policy					X
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document					X

101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104.1	Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101)	X

* Indicates management contract or compensatory plan or arrangement.

† Certain identified information has been excluded from the exhibit because it both (A) is not material and (B) would be competitively harmful if publicly disclosed.

ITEM 16. FORM 10-K SUMMARY

Not included.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

OMEROS CORPORATION

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

Dated: April 1, 2024

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ GREGORY A. DEMOPULOS, M.D. Gregory A. Demopulos, M.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	April 1, 2024
/s/ MICHAEL A. JACOBSEN Michael A. Jacobsen	Vice President, Finance, Chief Accounting Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	April 1, 2024
/s/ THOMAS F. BUMOL, PH.D. Thomas F. Bumol, Ph.D.	Director	April 1, 2024
/s/ THOMAS J. CABLE Thomas J. Cable	Director	April 1, 2024
/s/ PETER A. DEMOPULOS, M.D. Peter A. Demopulos, M.D.	Director	April 1, 2024
/s/ ARNOLD C. HANISH Arnold C. Hanish	Director	April 1, 2024
/s/ LEROY E. HOOD, M.D., PH.D. Leroy E. Hood, M.D., Ph.D.	Director	April 1, 2024
/s/ DIANA PERKINSON, M.D. Diana Perkinson, M.D.	Director	April 1, 2024
 Rajiv Shah, M.D.	Director	April 1, 2024

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CONTACTS + INFORMATION

Corporate Headquarters

Omeros Corporation
The Omeros Building
201 Elliott Avenue West
Seattle, WA 98119
206.676.5000
www.omeros.com

2024 Annual Meeting

The 2024 Annual Meeting of Shareholders of Omeros Corporation will be held via webcast on the Internet on Thursday, June 6, 2024, beginning at 10:00 A.M. (Pacific time), at www.virtualshareholdermeeting.com/OMER2024.

Investor Relations

Investors can contact Omeros Investor Relations by email at ir@omeros.com, by calling 206.676.5000, or by writing to Investor Relations at Omeros' corporate headquarters.

Copies of Omeros' Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including financial statements, as well as other Omeros public documents, are available on the Omeros investor relations website at investor.omeros.com or by written or telephonic request to Investor Relations at Omeros' corporate headquarters.

Transfer Agent and Registrar

Computershare Inc.
P.O. Box 43078
Providence, RI 02940-3078
Toll Free Number: 866.282.4938 (U.S.) Outside the U.S.: 201.680.6578
TDD for Hearing Impaired: 800.490.1493 (U.S.) Outside the U.S.: 781.575.4592
www.computershare.com/investor

Independent Registered Public Accounting Firm

Ernst & Young LLP

Stock Listing

Omeros' stock trades on The Nasdaq Global Market under the symbol OMER. For more information, please visit www.omeros.com.

BOARD OF DIRECTORS

Thomas F. Bumol, Ph.D.
Former Executive Vice President
Allen Institute for Immunology

Thomas J. Cable
Vice Chairman of the Board
Washington Research Foundation

Gregory A. Demopulos, M.D.
Chairman and President
Chief Executive Officer
Omeros Corporation

Peter A. Demopulos, M.D.
Cardiologist
Swedish Heart and Vascular Institute

Arnold C. Hanish
Former VP and Chief Accounting Officer
Eli Lilly and Company

Leroy E. Hood, M.D., Ph.D.
Chief Strategy Officer
Institute for Systems Biology
Chief Executive Officer
Phenome Health

DianaT. Perkinson, M.D.
Physician
MD² International LLC

Rajiv Shah, M.D.
President
The Rockefeller Foundation
Former Administrator of the
U.S. Agency for International Development

EXECUTIVE OFFICERS

Gregory A. Demopulos, M.D.
Chairman and President
Chief Executive Officer

Michael A. Jacobsen
Vice President, Finance
Chief Accounting Officer and Treasurer

Peter B. Cancelmo, J.D.
Vice President,
General Counsel and Secretary

SIGNIFICANT EMPLOYEES

Nadia Dac
Vice President, Chief Commercial Officer

Mariana N. Dimitrova , Ph.D.
Vice President,
Chemistry, Manufacturing and Controls

George A. Gaitanaris, M.D., Ph.D.
Vice President, Science
Chief Scientific Officer

Andreas Grauer, M.D.
Vice President, Chief Medical Officer

Catherine A. Melfi, Ph.D.
Vice President, Regulatory Affairs & Quality Systems
Chief Regulatory Officer

J. Steven Whitaker, M.D., J.D.
Vice President, Clinical Development

Peter W. Williams
Vice President, Human Resources

FORWARD-LOOKING STATEMENTS

This annual report 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 annual report. Omeros' actual results could differ materially from those anticipated in these forward-looking statements for many reasons including, without limitation, the risks, uncertainties and other factors described under the heading "Risk Factors" in this annual report. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and Omeros assumes no obligation to update these forward-looking statements, even if new information becomes available in the future.

THE OMEROS BUILDING
201 ELLIOTT AVENUE WEST
SEATTLE, WA 98119
OMEROS.COM