



**OMEROS®**

**OMEROS  
CORPORATION**

**2024  
ANNUAL  
REPORT**

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LET SCIENCE LEAD THE WAY®

May 30, 2025



**Dear Fellow Shareholders:**

2024 was a year of significant progress for Omeros Corporation, marked by important clinical and regulatory advancements across our pipeline, moving us closer to delivering multiple first-in-class therapeutics to patients in indications for which there is no approved treatment or that hold substantial unmet need. At the same time, we recognize that conditions in our industry and the broader economy have become more challenging in 2025, and that these conditions might remain unpredictable for the foreseeable future. Despite these challenges, we remain focused on successfully bringing narsoplimab to market, advancing our highest-value programs, and delivering value to our shareholders. Our accomplishments during 2024 demonstrate the quality of our programs, the strength of our science, and our commitment to the betterment of patients.

In 2024, we finalized with input from FDA the protocol and statistical analysis plan to compare survival of patients with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA) treated with narsoplimab, our lead MASP-2/lectin pathway inhibitor, to that of TA-TMA patients in an external control registry who were not treated with narsoplimab. The analyses were conducted by an independent statistics group and results, which were announced in late 2024 and early 2025, reinforced what we had previously observed: narsoplimab significantly improves survival in patients with TA-TMA. In the primary statistical analysis comparing overall survival in the 28 TA-TMA patients in our previously conducted pivotal trial for narsoplimab in TA-TMA to the external control, narsoplimab met its primary endpoint, with narsoplimab-treated patients demonstrating clinically meaningful and statistically significant superiority in overall survival – a hazard ratio of 0.32 (representing a three-fold improvement in overall survival; 95% confidence interval: 0.23 to 0.44) with p-value less than 0.00001 – compared to the TA-TMA registry patients. Analyses comparing overall survival of narsoplimab-treated TA-TMA patients enrolled in our global expanded access program to that in the same control registry of well-matched TA-TMA patients showed a similarly strong survival benefit with narsoplimab treatment, as did prespecified primary-related and EAP-related sensitivity analyses. Collectively, the results strongly support the robustness of narsoplimab's effect on survival in at-risk TA-TMA patients. These results formed the basis of our Biologics License Application (BLA) for narsoplimab in TA-TMA, which we submitted to the U.S. Food and Drug Administration in the first quarter of this year. FDA accepted the BLA and assigned a Prescription Drug User Fee Act (PDUFA) target action date of September 25, 2025. This marks an important milestone for Omeros and for patients suffering from this life-threatening complication of stem cell transplantation.

We also made significant progress in our MASP-3 inhibitor program targeting the alternative pathway of complement. In 2024, we substantially completed two Phase 2 trials evaluating our lead MASP-3 inhibitor zaltenibart (OMS906) for the treatment of paroxysmal nocturnal hemoglobinuria (PNH)—one in treatment-naïve patients and another in patients with suboptimal response to C5 inhibitors. Results to date from both studies have shown strong efficacy and a favorable safety profile, positioning us to initiate Phase 3 development in the first quarter of 2025. Zaltenibart, which we believe is a “pipeline in a drug” given its potential for broad applicability across multiple therapeutic areas and indications, was also granted rare pediatric disease designation by the FDA for the treatment of complement 3 glomerulopathy (C3G).

Beyond our complement-focused programs, we advanced work with OMS527, our orally administered phosphodiesterase-7 inhibitor being developed for the broad treatment of addictive and compulsive disorders. With funding from the National Institute on Drug Abuse (NIDA), we successfully completed pre-clinical OMS527-cocaine-drug interaction studies, and work is now underway to initiate the planned Phase 1b clinical in-patient

trial evaluating OMS527 for cocaine use disorder, also fully funded by NIDA, with results expected in late 2025 or early 2026.

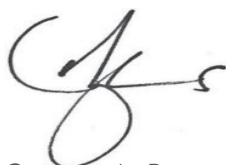
Our T-CAT platform, novel pathogen-targeting recombinant antibodies designed for broad applicability against diverse microbial species without promoting or enhancing the development of drug resistance, also made significant progress. The platform's current focus is the treatment of multidrug-resistant organisms, which represent a growing global medical and economic threat.

Omeros' novel oncology platform remains a dynamic area of innovation, producing strong preclinical data across multiple programs. These programs are designed to overcome key limitations of current cancer therapies. We look forward to continuing the strong momentum of these programs while advancing opportunities for clinical translation.

Overall, 2024 represents what appears to be a watershed year for Omeros, marked by significant progress across all our platforms and programs. As we look forward to the upcoming FDA decision on the narsoplimab BLA for the treatment of TA-TMA, all of us at Omeros remain committed to succeeding in our mission to develop therapeutics that profoundly enhance the lives of the patients we serve.

We thank you for your continued support and confidence.

Sincerely,

A handwritten signature in black ink, appearing to be 'G. Demopoulos', with a stylized flourish at the end.

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



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

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**FORM 10-K**

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(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, 2024

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

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**OMEROS CORPORATION**  
(Exact name of registrant as specified in its charter)

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Washington  
(State or other jurisdiction of  
incorporation or organization)

91-1663741  
(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

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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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 \$224,794,965.

As of March 25, 2025, the number of outstanding shares of the registrant’s common stock, par value \$0.01 per share, was 58,063,901.

#### DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant’s proxy statement with respect to the 2025 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, 2024, are incorporated by reference into Part III of this Form 10-K.

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## 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 ability to comply with the terms of our secured credit facility and our expectations regarding the effect on our operations of compliance with the restrictive covenants and other obligations applicable under our secured credit facility;
- our expectations regarding amounts potentially payable to us based on sales of our former commercial ophthalmology product OMIDRIA®;
- our expectations regarding anticipated or potential paths to regulatory approval of narsoplimab by the U.S. Food and Drug Administration (“FDA”) and/or the European Medicines Agency (“EMA”), including whether our resubmitted biologics license application (“BLA”) for narsoplimab in hematopoietic stem cell transplant-associated thrombotic microangiopathy (“TA-TMA”) will be accepted and reviewed by FDA, whether and when a marketing authorization application (“MAA”) may be submitted to the EMA for narsoplimab in any indication, and whether and when FDA, the EMA or any other regulatory authority will grant approval for narsoplimab in TA-TMA or in any other indication;
- our expectation that our contract manufacturer will provide support needed in connection with FDA’s review of the manufacturing sections of our BLA for narsoplimab in TA-TMA, including in connection with any regulatory inspection of the relevant facility and/or manufacturing process, and, if narsoplimab is approved for marketing, our expectation that our contract manufacturer will manufacture narsoplimab in amounts sufficient to supply our commercial needs;
- 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 expectations regarding the clinical, therapeutic and competitive benefits and importance of our product candidates, including narsoplimab and zaltenibart;
- our ability to design, initiate and/or successfully complete clinical trials and other studies for our product 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 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 product 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 product 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 product candidates, programs and operations include, but are not limited to, the following:

- management has concluded that there is substantial doubt regarding our ability to continue as a going concern;
- inability to raise capital when needed;
- restrictions imposed by our secured credit facility and our ability to comply with such restrictions;
- our indebtedness and liabilities could limit the cash flow available for our operations;
- 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 product 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;
- changes to the size, structure, powers and operations of the U.S. federal government may cause economic disruptions;
- 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 product 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;
- 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

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;
- the impact of anti-takeover provisions in our charter documents and under Washington law on potential acquisitions of our company; and
- our inability to pay dividends.

**OMEROS CORPORATION**  
**ANNUAL REPORT ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2024**

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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 product candidate in our pipeline of complement-targeted therapeutics, is a proprietary, patented human monoclonal antibody inhibitor of MASP-2, the key activator 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, our long-acting antibody and an orally administered small molecule targeting MASP-2 and the lectin pathway.

The lead product candidate in our development program focused on the alternative pathway of complement is zaltenibart (OMS906), a proprietary, patented monoclonal antibody targeting MASP-3. MASP-3 is the key and most proximal activator of the alternative pathway of complement. We believe zaltenibart has the potential to treat a wide range of alternative pathway-related diseases and that its attributes favorably differentiate zaltenibart from other marketed and in-development alternative pathway inhibitors. Clinical development of zaltenibart is currently ongoing in multiple alternative pathway-related disorders, including paroxysmal nocturnal hemoglobinuria (“PNH”), a rare and life-threatening hemolytic blood disorder, and complement 3 glomerulopathy (“C3G”), a rare chronic kidney disease. A small molecule MASP-3 inhibitor intended for oral administration 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 an oncology platform directed to development of novel therapeutics across a portfolio of signaling-driven immunomodulators, oncotoxins and an adoptive T-cell technology combined with an immunostimulator.

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 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 at the closing and we retained all outstanding accounts receivable, accounts payable, and accrued expenses as of the closing date. In February 2023, we received a \$200.0 million milestone payment from Rayner (the “Milestone Payment”), plus accrued interest, upon an event (the “Milestone Event”) that established separate payment for OMIDRIA for a continuous period of at least four years when furnished in an ambulatory surgery center (“ASC”) setting. The Asset Purchase Agreement also provides for the payment of royalties by Rayner 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 longest of which in the United States is currently into 2035. The applicable royalty rates are currently 30% in the United States and 15% outside the United States, subject to reduction upon certain events described in the Asset Purchase Agreement.

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 exchange for a portion of the royalties to which we were entitled from Rayner under the Asset Purchase Agreement on global net sales of OMIDRIA between September 1, 2022 and December 31, 2030, subject to certain annual caps on the royalty amounts payable to DRI.

On February 1, 2024, we entered into an Amended and Restated Royalty Purchase Agreement (the “Amendment”) under which we sold to DRI 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 receive all royalties on U.S. net sales of OMIDRIA payable between January 1, 2024 and December 31, 2031. We received \$115.5 million 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 our 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. For further discussion, please refer to Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations – OMIDRIA Sale and Royalty Monetization Transactions.”

#### *2024 Term Loan*

On June 3, 2024, we, with certain subsidiaries, as guarantors, entered into a Credit and Guaranty Agreement (the “Credit Agreement”) with certain funds managed by Athyrium Capital Management, LP (collectively, “Athyrium”) and certain funds managed by Highbridge Capital Management, LLC (collectively, “Highbridge”) as lenders and Wilmington Savings Fund Society, FSB, as administrative agent and collateral agent. We have borrowed approximately \$67.1 million under the Credit Agreement and pledged substantially all of our assets, including our intellectual property, as collateral, subject to customary exceptions, and excluding royalty interests in OMIDRIA and certain related rights. Pursuant to a covenant in the Credit Agreement, we must maintain \$25.0 million of unrestricted cash, cash equivalents and short-term investments at all times. In addition, the Credit Agreement restricts or places conditions on, among other things, our ability to incur indebtedness, grant liens, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay cash dividends or make distributions, repurchase stock, repurchase our 5.25% convertible senior notes due on February 15, 2026 (the “2026 Notes”), license certain of our intellectual property on an exclusive basis and engage in significant business transactions such as a change of control. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. For additional information regarding the Credit Agreement and its associated risks, see Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations – 2024 Term Loan and Repurchase of 2026 Notes” and Part I, Item 1A, “Risk Factors” in this Annual Report on Form 10-K.

## Our Product Candidates and Development Programs

Our clinical product candidates consist of the following:

Product Candidate/Program	Targeted Disease(s)	Development Status	Next Expected Milestone
Narsoplimab (MASP-2 / Lectin Pathway)	Hematopoietic stem-cell transplant-associated thrombotic microangiopathy (TA-TMA)	Resubmission of BLA completed	FDA review of BLA; submission of MAA to EMA
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 ARDS and related indications
OMS1029 (MASP-2 / Lectin Pathway)	Long-acting second-generation antibody targeting lectin pathway disorders	Phase 1 studies completed	Select indication for Phase 2 development
Zaltenibart (MASP-3 / Alternative Pathway)	Paroxysmal nocturnal hemoglobinuria (PNH)	Phase 3 programs initiated	Complete Phase 3 clinical trials
Zaltenibart (MASP-3 / Alternative Pathway)	Complement 3 glomerulopathy (C3G) and other alternative pathway disorders	Phase 2 program ongoing	Complete Phase 2 study and initiate Phase 3 clinical trial
OMS527 (PDE7)	Cocaine use disorder (CUD); other addictive and compulsive disorders; movement disorders	Phase 1b study in adult CUD patients initiating with committed funding from National Institute on Drug Abuse (NIDA)	Complete NIDA-funded Phase 1b clinical trial in patients with cocaine use disorder

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	Assess preclinical data on current drug development candidate
MASP-3: small-molecule inhibitors	Alternative pathway disorders	Preclinical	Identify drug development candidate for clinical trials
Adoptive T-Cell and Immunostimulator Combination Therapies	Wide range of cancers	Preclinical	Complete preclinical proof of concept studies and evaluate data
Oncotoxins and Immunomodulators	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. We are focused on development of therapeutics to treat diseases associated with the lectin and/or alternative pathways of complement. We are developing antibodies as well as small-molecule inhibitors of key enzymes known to be centrally involved in the activation of the targeted pathway 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 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 product candidate in our pipeline of complement-targeted therapeutics 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”)*: In March 2025, we resubmitted to FDA a BLA seeking marketing approval for narsoplimab in TA-TMA. FDA has 30 days to decide whether the application is sufficiently complete to permit a review of the BLA. Assuming FDA agrees to review the BLA, we expect the resubmission to be classified as Type B, meaning that the target date for FDA action on the BLA under the Prescription Drug User Fee Act (“PDUFA”) is expected to be in September 2025. As with any BLA or new drug application, there can be no guarantee that, even if FDA agrees to review the BLA, that FDA will complete its review within a given timeframe, or that our BLA will ultimately be approved.

We previously submitted a BLA for narsoplimab in TA-TMA, the clinical sections of which were based on results of the pivotal trial of narsoplimab in TA-TMA (OMS721-TMA-001), in which the drug met its primary endpoint of complete response compared to an efficacy threshold, where complete response required clinical improvements in TMA markers (platelet count and lactose dehydrogenase) and in organ function (renal pulmonary, gastrointestinal or neurological) or freedom from transfusion. Despite the success on the primary endpoint and the unmet need in TA-TMA, in October 2021 FDA issued a complete response letter (“CRL”) with respect to the original BLA and 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, including paths based on comparison of survival data from the completed pivotal trial versus a historical control group.

Based on the recommendations included in the appeal decision and on subsequent interactions with FDA, we proposed a statistical analysis plan to assess data from our pivotal clinical trial, existing data from a historical control population available from an external source and data from the narsoplimab expanded access program. The proposed protocol and statistical analysis plan were reviewed by FDA, and FDA’s recommendations were incorporated into the final versions. All statistical analyses were conducted by an independent statistical group and the completed analyses are included in the resubmitted BLA for narsoplimab in TA-TMA.

The primary endpoint under the statistical analysis plan compared to overall survival in the 28 TA-TMA patients that received narsoplimab treatment in the OMS721-TMA-001 pivotal trial to overall survival of more than 100 similarly high-risk TA-TMA patients in an external control registry who did not receive narsoplimab treatment. The OMS721-TMA-001 patients demonstrated clinically meaningful and statistically significant superiority in overall survival – a hazard ratio of 0.32 (95% confidence interval: 0.23 to 0.44) with p-value less than 0.00001 – compared to the TA-TMA patients in the external registry. The robustness of these results is supported by the sensitivity analyses conducted, and confidence in the results is demonstrated by statistical tests intended to assess potential confounding effects.

Analyses similar to the primary analysis comparing survival in TA-TMA patients treated with narsoplimab under a global expanded access program (“EAP”) to that of similarly at-risk TA-TMA registry of patients were also included in the analysis plan, along with sensitivity analyses related to each of the primary and EAP comparisons.

The EAP-related analyses, which compare survival in narsoplimab-treated adult EAP patients and survival in similarly at-risk TA-TMA patients in the external control registry, further support the robustness and generalizability of the primary analysis results, with representative analyses of the combined EAP and pivotal trial patients yielding hazard ratios ranging from 0.34 (95% confidence interval: 0.21, 0.53) to 0.46 (95% confidence interval: 0.35, 0.60) and p-values ranging from less than 0.00001 to 0.00002. Results of the primary-related and EAP-related sensitivity analyses performed as part of the statistical analysis plan support the robustness of the primary results. The EAP includes adults and children and includes both treatment-naïve patients and patients who failed or stopped treatment for their TA-TMA prior to receiving narsoplimab. Analyses of survival across all of these subgroups of patients treated with narsoplimab show consistently impressive survival results regardless of age or prior treatment status.

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 are targeting to complete our MAA submission in the first half of 2025.



*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 acute respiratory distress syndrome (“ARDS”), and we have developed mechanistic, *in vivo* animal data, and proof-of-concept clinical data indicating that narsoplimab may be an effective therapeutic for COVID-19, ARDS and/or related indications. We have also generated compelling data in established animal models across all forms of severe ARDS - bacterial, viral and chemical - and continue to explore the evidence that MASP-2 and the lectin pathway are important drivers of post-acute sequelae SARS-CoV-2 (“PASC”), commonly known as long COVID.

We have also developed an assay platform to identify hyperactivation of the lectin pathway. Because 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, the assay may be useful to identify patients with these conditions 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 and 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 and/or ARDS.

### 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. We have completed Phase 1 clinical trials evaluating both single-ascending and multiple-ascending doses of OMS1029. Data from these trials demonstrated the feasibility of once quarterly, subcutaneous administration, representing a convenient regimen well-suited for chronically dosed indications that can be administered either in health care centers or at home. OMS1029 has been well tolerated to date with no safety concerns identified. We continue to evaluate several potential indications for which Phase 2 clinical development of OMS1029 could be pursued, depending on resource availability. OMS1029 drug product and placebo have been manufactured and stored for future use. Available quantities are expected to be sufficient to support a Phase 2 clinical trial.

### *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.

### Zaltenibart (OMS906)

The lead product candidate in our MASP-3 inhibitor program is zaltenibart (previously referred to as OMS906), a proprietary, patented human monoclonal antibody targeting MASP-3. Clinical development of zaltenibart is ongoing in PNH and C3G. Zaltenibart has been well tolerated to date across all clinical trials, and no safety signal of concern has been identified.

### *Paroxysmal nocturnal hemoglobinuria (“PNH”)*:

Our program evaluating zaltenibart in PNH is in Phase 3 of development. Similar to our Phase 2 program, our Phase 3 program includes both a study treating PNH patients who are not receiving treatment with a complement inhibitor, as well as a “switch-over” study in PNH patients who have had an unsatisfactory response to eculizumab and ravulizumab, both of which are inhibitors of complement component 5 (“C5”).

In the fall of 2024, we met with FDA and European regulators to discuss further details of our planned Phase 3 program for zaltenibart in PNH. With both regulatory agencies, we discussed data developed from our clinical and nonclinical programs to date and our Phase 3 development plans for zaltenibart in PNH. Both regulatory agencies agreed with the trial designs and provided other valuable feedback to inform our development plans.

Both studies in our Phase 3 program are designed to provide head-to-head comparisons with the C5 inhibitors and could produce data demonstrating the superiority of zaltenibart over the C5 inhibitors in these patient populations. These data could form the basis for comparative superiority claims for promotion, enhanced market access, and pricing reflective of zaltenibart's advantages. We also sought and received recommendations regarding patient-reported-outcome measures from the German Federal Joint Committee, which determines availability of reimbursement from statutory health insurance funds in that country and which has specialized expertise in patient-reported-outcome measures. Recommended patient-reported-outcome measures were incorporated into the zaltenibart Phase 3 program and are expected to be helpful in securing appropriate pricing in relevant jurisdictions.

Clinical site activation in our Phase 3 program for PNH has begun. All zaltenibart drug product needed for our Phase 3 programs has been manufactured and active comparator drug has been sourced. A total of 120 clinical investigative sites across 30 countries have been chosen for clinical trial participation in the zaltenibart Phase 3 program in PNH. A number of these sites have already identified pools of PNH patients ready to participate in the zaltenibart trials, and Omeros continues collaborating with sites to identify additional eligible and already available PNH patients.

Our Phase 2 development program evaluating zaltenibart for PNH consists of three studies. A study in PNH patients who have had an unsatisfactory response to the C5 inhibitor ravulizumab has been completed. A study in PNH patients who have not previously been treated with a complement inhibitor is ongoing under protocol amendments intended to produce additional data on the zaltenibart dose selected for Phase 3 development. The third clinical trial in our Phase 2 program evaluating zaltenibart in PNH is an ongoing open-label extension study to assess the long-term efficacy and safety of zaltenibart in patients who have completed any of our PNH clinical trials. Data from the extension study are expected to contribute to any future marketing applications for zaltenibart in the treatment of PNH.

Results from a pre-specified interim analysis in our Phase 2 clinical trial of zaltenibart in complement-inhibitor-naïve adults with PNH were featured in a podium presentation at the annual meeting of the American Society of Hematology in December 2023. The interim analysis results showed statistically significant and clinically meaningful improvements in all measured markers of hemolysis, including hemoglobin and lactate dehydrogenase. This study was amended to gather additional data on the zaltenibart dose selected for Phase 3 development and remains ongoing for this purpose.

The last patient visit in our Phase 2 trial evaluating two doses of zaltenibart in PNH patients who have had an unsatisfactory response to the C5 inhibitor ravulizumab occurred in October 2024. Utilizing a "switch-over" design, this study enrolled PNH patients receiving ravulizumab, added zaltenibart to provide combination therapy with ravulizumab for 24 weeks, and then, in those patients who demonstrated a hemoglobin response with the combination therapy, switched to zaltenibart monotherapy. In June 2024, efficacy data from a pre-specified interim analysis of the combination therapy portion of the trial were featured in a podium presentation at the annual congress of the European Hematology Association held in Madrid, Spain. The interim analysis showed that the addition of zaltenibart therapy to ravulizumab treatment resulted in statistically significant and clinically meaningful improvements in both mean hemoglobin levels and absolute reticulocyte counts by week 4 of combination therapy, with a sustained response observed through week 24 (the latest assessment prior to the interim analysis cutoff). All 13 enrolled patients were included in the interim analysis. All patients in the high-dose group achieved clinical response, defined as an increase in hemoglobin of at least 2 grams, and six of seven patients in the low-dose group achieved this same clinical response. Data from the monotherapy portion of the trial were presented at the annual meeting of the American Society of Hematology in December 2024. Twelve of 13 enrolled patients continued to the second stage of the study. The interim results from the monotherapy stage of the study showed that in PNH patients experiencing substantial extravascular hemolysis while receiving ravulizumab, zaltenibart monotherapy resulted in sustained clinically meaningful improvements in both hemoglobin and absolute reticulocyte count and prevented both intravascular and extravascular hemolysis.

Zaltenibart received designation from FDA as an orphan drug for the treatment of PNH in July 2022.

*Complement 3 glomerulopathy ("C3G"):* We also have an ongoing Phase 2 clinical program evaluating zaltenibart 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 two Phase 3 trials with other inhibitors of the alternative pathway that reported positive results in the treatment of C3G. Sites for the zaltenibart Phase 2 trial in C3G are open to enrollment in multiple countries and dosing in the study is ongoing. We are amending the study to include a cohort of patients with C3G who have normal plasma C3 levels and evidence of renal inflammation in their urine, which represents a large proportion of the total C3G population. Our Phase 2 study in C3G requires enrollment of a relatively small number of patients and we expect to complete the study later this year. Following completion of the Phase 2 study, and assuming strong evidence of efficacy, we plan to initiate a Phase 3 trial in C3G.

In October 2024, zaltenibart received a rare pediatric disease designation from FDA for the treatment of C3G. Companies awarded a rare pediatric disease designation are eligible to receive a rare pediatric disease priority review voucher from FDA if the designated drug's first approval is for the associated indication in the pediatric population and certain other criteria are met. Absent legislative reauthorization and extension of the priority review voucher program for rare pediatric disease, one of the criteria for receipt of a voucher under the current law is that the drug must be approved by September 30, 2026. The holder of a priority review voucher is entitled to obtain a priority review by FDA of either a new drug application or a biologics license application for a different

product and/or indication, reducing the review time and accelerating any grant of approval and subsequent market entry by at least four months. The voucher may be used by the original recipient, or it can be sold for use to another company.

### *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 develop and assess preclinical data on our selected drug candidate. Our MASP-3 small-molecule inhibitor is advancing toward selection of a drug development candidate.

### **Other Clinical Programs**

#### *PDE7 Inhibitor Programs - OMS527*

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. 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 (“NIDA”), part of the National Institutes of Health, and requested by NIDA to develop our lead orally administered PDE7 inhibitor compound for the treatment of CUD. The award, for a total of \$6.24 million over three years is intended to fund an in-patient, placebo-controlled clinical study evaluating the safety and effectiveness of OMS527 in adults with CUD who receive concurrent intravenous cocaine, as well as prerequisite cocaine-OMS527 interaction safety studies in which the OMS527 therapeutic candidate was co-administered with cocaine in two animal species to rule out enhancement of the detrimental effects of cocaine.

In the OMS527-cocaine interaction studies, OMS527, when administered at two different doses in combination with cocaine, did not produce an additive or synergistic effect on the convulsive threshold of cocaine in rats or on the adverse cocaine-induced cardiovascular responses in non-human primates. Instead, the higher doses of OMS527 generally lessened the severity of effects noted following intravenous administration of cocaine, most notably decreasing convulsant-related activity following the administration of cocaine.

Based on the successful outcome of the preclinical studies, NIDA has provided the Company with a funding commitment for the year commencing April 1, 2025 in the amount of \$4.02 million. This amount is expected to fund the inpatient clinical trial assessing safety and efficacy of the lead OMS527 compound in adult patients with CUD. Readout of preliminary data from that study is targeted by year-end 2025.

In a previously completed Phase 1 clinical trial in healthy human subjects the lead OMS527 compound was well tolerated with no safety signal of concern and displayed favorable pharmacokinetics, supporting once daily dosing in the dose range expected to produce efficacy in humans.

*Levodopa-induced dyskinesia (“LID”)*: With investigators at Emory University, we are also evaluating an OMS527 PDE7 inhibitor 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.

#### *PPAR $\gamma$ Program - OMS405*

In our peroxisome proliferator-activated receptor gamma (“PPAR $\gamma$ ”) program, we have engaged in development of proprietary compositions that include PPAR $\gamma$  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 PPAR $\gamma$  and addiction disorders. Data from clinical studies and from animal models of addiction suggest that PPAR $\gamma$  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 PPAR $\gamma$  program. These studies evaluated a PPAR $\gamma$  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 PPAR $\gamma$  agonist significantly reduced heroin craving and overall anxiety. 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 PPAR $\gamma$  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 PPAR $\gamma$  agonist in patients with cocaine use disorder. An investigator-sponsored study evaluating the effects of a PPAR $\gamma$  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 PPAR $\gamma$  program, as described under “Intellectual Property” below.

## **Preclinical Programs and Platforms**

### *Oncology Platform*

The objective of our oncology program is to move beyond existing targeted biologics, such as antibody-drug conjugates (“ADC”), which have small therapeutic indexes and limited tissue penetrance, and beyond engineered cellular-therapies, such as CAR-T cells, which are expensive and time-consuming. Building on our understanding of immunity, both innate, *e.g.*, complement-mediated, and adaptive, meaning B-cells as well as CD4 and CD8 T-cells, we are developing a portfolio of next generation biologics to treat cancer. It consists of new modalities of targeted drug conjugates, with better therapeutic indexes and better tissue penetrance, which we believe could eventually sideline the current ADC technology. Our portfolio also includes an adoptive T-cell technology combined with an immunostimulator that is easier, faster and cheaper than current cellular therapy approaches. Our technology also maintains an enhanced anti-cancer immune response through subsequent repetitive and simple therapeutic administrations.

Our oncology development program is operating in stealth mode as we continue to confirm our results and to generate new data which we expect will contribute to our intellectual property position.

## **Sales and Marketing**

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

If narsoplimab is approved for marketing in the United States for treatment of TA-TMA, we expect to utilize an internal sales force to sell the product. We have hired a head of sales for narsoplimab, along with regional leaders of our planned U.S. sales force and intend to begin hiring specialty sales representatives for U.S. field sales upon reaching certain milestones associated with FDA’s review of our BLA for narsoplimab. If our anticipated MAA for narsoplimab in TA-TMA is approved by the EMA, we intend to enter into partnerships and/or commercial services arrangements with third-parties to market and sell narsoplimab in Europe and are currently evaluating various potential arrangements for commercialization in Europe.

## **Manufacturing, Supply and Commercial Operations**

We have laboratories in-house for analytical method development, bioanalytical testing, formulation, stability testing and small-scale compounding of laboratory supplies of product candidates; however, we do not own or operate internal manufacturing facilities capable of producing sufficient quantities of our product candidates under current Good Manufacturing Practices (“cGMP”) for use in clinical studies, or for the manufacture of narsoplimab for commercial use following potential regulatory approval.

We utilize contract manufacturers to produce sufficient quantities of product candidates for use in preclinical and clinical studies and to store and distribute our product candidates. We require manufacturers that produce bulk drug substance and finished drug products for clinical use to operate in accordance with cGMP and all other applicable laws and regulations. We anticipate that we will rely on contract manufacturers to develop and manufacture our product 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 product 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.

We have a Combined Development and Commercial Supply Agreement, effective May 16, 2018, with Vetter Pharma International, GmbH (“Vetter”) under which the process for manufacturing of sterile liquid vials pre-filled with finished narsoplimab was developed and validated, and pursuant to which Vetter has agreed to aseptically fill narsoplimab in vials for clinical or commercial use. Under the agreement, we must provide Vetter with non-binding rolling forecasts of our long-term supply requirements on a periodic basis and submit purchase orders for filled narsoplimab vials intended for commercial use for confirmation by Vetter within an agreed time before the anticipated delivery date. Pricing for commercial manufacturing services varies based on the number of batches ordered and may be adjusted periodically, subject to limitations specified in the agreement. For commercial-stage manufacturing, each batch ordered must be for a quantity of finished units that is at least equal to a specified minimum but no more than a specified maximum per batch. We may be obligated to pay certain fees to Vetter upon cancellation purchase orders or in connection with postponement of batches subject to a purchase order. The agreement is effective with respect to the commercial work contemplated thereunder for an initial term five years after which it automatically renews for two-year terms unless either party notifies the other party at least 12 months before the end of the then-current term that it does not intend to renew. In addition, either party may terminate the agreement under certain circumstances, subject to applicable notice and cure periods.

In addition to our agreements with Lonza and Vetter, we utilize a third-party vendor for labelling and final packaging of narsoplimab finished goods. We expect to utilize one or more wholesalers for distribution of narsoplimab, if approved in the U.S. for commercial sale.

We have not entered into commercial supply agreements for any of our product candidates other than 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 zaltenibart 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 zaltenibart program. We expect that an additional \$10.0 million milestone payment will become due during 2025, pending the anticipated achievement later this year of an additional clinical development milestone in our zaltenibart 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 product 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.

*Product 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), PiaSky® (crovalimab-akkz), Voydeya (danicopan) and Fabhalta® (iptacopan). Narsoplimab, OMS1029 and/or zaltenibart will face competition from branded and/or generic versions of 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 product candidates and programs. Some of our product 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 March 31, 2025, we owned or held worldwide exclusive licenses to a total of 81 issued patents and 64 pending patent applications in the U.S. and 1,443 issued patents and 655 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 March 31, 2025, we exclusively controlled 42 issued patents and 33 pending patent applications in the U.S., and 861 issued patents and 474 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 - Zaltenibart (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 zaltenibart, as well as the option to obtain additional licenses to such technology for exclusive application to additional antibodies that we may select. As of March 31, 2025, we exclusively controlled five issued patents and eight pending patent applications in the U.S. and 212 issued and 109 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.
- *PPAR $\gamma$  Program - OMS405*. As of March 31, 2025, we owned three issued patents and one pending patent application in the U.S., and 42 issued patents and one pending patent application in foreign markets, directed to our discoveries linking PPAR $\gamma$  and addictive disorders. Our PPAR $\gamma$ -related patents have terms that will expire as late as 2030.
- *PDE7 Program - OMS527*. As of March 31, 2025, we owned two issued patents and two pending patent applications in the U.S., and 61 issued patents and seven pending patent applications in foreign markets directed to our discoveries linking PDE7 to movement disorders, as well as three issued patents and two pending patent applications in the U.S., and 54 issued patents and six 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” above.
- *Oncology Program*. Our oncology program comprises novel platforms and technologies related to potential therapies for cancer. We are operating the oncology program in stealth mode as we continue to confirm our results and to generate new data which we expect will contribute to our intellectual property position. As of March 31, 2025, we had two patent applications pending in the U.S. directed to a potential cancer therapeutic derived from our oncology platform.

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 product 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 product 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”, as well as the associated “alpha/omega” logo within the U.S. Patent and Trademark Office (“USPTO”) and various foreign jurisdictions in connection with the products and services we offer. We also have registered and pending trademark applications within the USPTO and in certain foreign jurisdictions directed to the trademark “YARTEMLEA”, the brand name under which we expect to market narsoplimab if the drug is approved for commercial sale. We are not aware of any material claims of infringement or other challenges to our right to use our trademarks in the U.S. or any other jurisdiction.

## 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 product 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 product 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 product 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 product candidates are in various stages of testing and none of our product 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; in the EU Member States and in European Economic Area countries a Clinical Trial Application (“CTA”) is submitted to the Clinical Trials Information System; in other countries outside of the U.S. and Europe, a 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 (“GCP”), and cGMP; 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 GCP. 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 [ClinicalTrials.gov](https://clinicaltrials.gov), 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 an applicable clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of such 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 product 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 GCP 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 product candidate satisfied its endpoints with statistical significance during clinical trials, FDA could determine that the overall balance of risks and benefits for the product 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 product candidates, such as those from our MASP-2 and MASP-3 programs, are considered biologics because they are proteins that are greater than 40 amino acids in size. 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 product 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 cGMP 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 cGMP. 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 companies conduct confirmatory studies post-approval to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. FDA may also impose restrictions on distribution to assure safe use. Pursuant to 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 and describe 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 expedited procedures. 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 the applicable disease or condition is not likely to be recovered from U.S. sales for that product. The grant 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 product 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 or consumer 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 product candidates successfully, and to attract commercialization partners for our product 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 product candidates. Even with the availability of such studies, third-party private and/or governmental payers may not provide coverage and reimbursement for our product 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, legislation imposed 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.

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 Medicare manufacturer discount and inflation rebate obligations under the Inflation Reduction Act (the “IRA”).

We are unable to predict what additional legislation, regulations, policies, executive orders 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 product 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, 2024, we had 202 full-time employees, 136 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 seven with M.D.s and 41 with Ph.D.s., of whom six and 40, 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 March 13, 2025:

Name	Age	Position(s)
<b>Executive Officers:</b>		
Gregory A. Demopoulos, M.D.	66	President, Chief Executive Officer and Chairman of the Board of Directors
David J. Borges	61	Vice President, Finance, Chief Accounting Officer and Treasurer
Peter B. Cancelmo, J.D.	46	Vice President, General Counsel and Secretary
<b>Significant Employees:</b>		
Nadia Dac	55	Vice President, Chief Commercial Officer
Mariana N. Dimitrova, Ph.D.	59	Vice President, Chemistry, Manufacturing and Controls
George A. Gaitanaris, M.D., Ph.D.	68	Vice President, Science and Chief Scientific Officer
David W. Ghesquiere	58	Vice President, Chief Business Development Officer
Andreas Grauer, M.D.	64	Vice President, Chief Medical Officer
Catherine A. Melfi, Ph.D.	66	Vice President, Regulatory Affairs & Quality Systems and Chief Regulatory Officer
J. Steven Whitaker, M.D., J.D.	69	Vice President, Clinical Development
Peter W. Williams	57	Vice President, Human Resources

*Gregory A. Demopoulos, 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. Demopoulos completed his residency in orthopedic surgery at Stanford University and his fellowship training in hand and microvascular surgery at Duke University. Dr. Demopoulos 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. Demopoulos received his M.D. from the Stanford University School of Medicine and his B.S. from Stanford University. Dr. Demopoulos is the brother of Peter A. Demopoulos, M.D., a member of our board of directors.

*David J. Borges* has served as our vice president, finance, chief accounting officer and treasurer since June 2024. He joined Omeros in June 2020 as senior director, financial planning & analysis and served as associate vice president, financial planning & analysis from April 2022 to June 2024. Prior to joining Omeros, Mr. Borges served as vice president, finance and administration, at Bulletproof 360, Inc., a health and wellness company, where he directed and managed all aspects of corporate finance, accounting, information technology, human resources, facilities, and legal from October 2014 until October 2019. From May 2009 to June 2014, Mr. Borges served as chief financial officer and vice president of Advanced Refreshment LLC, a producer of private label bottled water and water-based beverages. From July 2001 to May 2009, Mr. Borges served as finance and business integration director at Merck & Co., Inc. (“Merck”), a biopharmaceutical company, after Merck acquired Rosetta Inpharmatics, where Mr. Borges had been serving as director of finance & administration/controller since 1998. Mr. Borges is a certified public accountant and received his B.S. in Commerce in Accounting from Santa Clara 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.

*David W. Ghesquiere* has served as our chief business development officer since August 2024. Prior to joining Omeros, Mr. Ghesquiere served as managing director of Adrenaline Venture & Advisory LLC, an international advisory firm, advising biotech and technology companies, which he founded in 2012. Mr. Ghesquiere served, from November 2013 to December 2023, as senior vice president, corporate & business development of NanoString Technologies, focusing on life science tools, informatics, and molecular diagnostics (acquired by Bruker Corporation). Mr. Ghesquiere served as senior vice president, corporate & business development at Dendreon Corporation, a biotechnology company, from 2011 to 2012. From 2005 until its acquisition by Astellas in 2010, Mr. Ghesquiere also held a variety of executive positions at OSI Pharmaceuticals, including senior vice-president of corporate & business development and managing director of OSI’s corporate venture capital arm. Earlier in his career, Mr. Ghesquiere served in business development and alliance management roles at Aventis Pharmaceuticals (acquired by Sanofi) and worked in product marketing/new product planning at Johnson & Johnson. Mr. Ghesquiere received his M.B.A. from the University of Western Ontario’s Ivey Business School and his B.A. in economics from the University of Western Ontario.

*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](http://www.omeros.com). We make available, free of charge through our investor relations website at [investor.omeros.com](http://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](http://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 Product Candidates, Programs and Operations**

**Management has concluded that a substantial doubt is deemed to exist concerning our ability to continue as a going concern.**

As further discussed in Part II, Item 8, “Note 1—Organization and Basis of Presentation” to our Consolidated Financial Statements in this Annual Report on Form 10-K, substantial doubt exists regarding our ability to continue as a going concern through one year from the issuance of the Company's consolidated financial statements included in this Annual Report on Form 10-K. Our financial statements do not include any adjustment relating to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern will require us to generate positive cash flow from operations, obtain additional financing, enter into strategic alliances and/or sell assets. Our limited cash resources, which are impacted by a covenant in the Credit Agreement requiring us to maintain \$25.0 million of unrestricted cash, cash equivalents and short-term investments at all times, and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into strategic alliances and/or make our scheduled debt payments on a timely basis or at all. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

**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 product candidates or to continue our other preclinical development programs.**

Our operations have consumed substantial amounts of cash since our incorporation. As of December 31, 2024, we had cash, cash equivalents and short-term investments of \$90.1 million. Our cash used in operations was \$148.8 million and our net loss for the year ended December 31, 2024 was \$156.8 million. Pursuant to a covenant in the Credit Agreement, we must maintain \$25.0 million of unrestricted cash, cash equivalents and short-term investments at all times. We expect to continue to spend substantial amounts to:

- initiate and conduct clinical trials and manufacture clinical and registration batches for our product candidates;
- continue our research and development in our programs;
- make principal, interest and fee payments as required under our 2026 Notes;
- make interest payments under the initial term loan of \$67.1 million provided pursuant to the Credit Agreement (the “Initial Term Loan”); and

- commercialize and launch product 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. In addition, pursuing debt financings, certain equity offerings or other strategic transactions may result in mandatory prepayments of the Initial Term Loan. 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 product 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.

**Our Credit Agreement places restrictions on our operating and financial flexibility and could, if we were to default, adversely affect our liquidity and ability to retain title to our assets.**

We have borrowed approximately \$67.1 million under the Credit Agreement and pledged substantially all of our assets, including our intellectual property, as collateral. The Credit Agreement restricts or places conditions on, among other things, our ability to incur indebtedness, grant liens, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay cash dividends or make distributions, repurchase stock, repurchase our 2026 Notes, license certain of our intellectual property on an exclusive basis and engage in significant business transactions such as a change of control. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. The failure to satisfy these or other obligations under the Credit Agreement could constitute an event of default, which could provide the lenders with a right to accelerate our repayment obligations under the Credit Agreement and to take control of our pledged assets, which includes substantially all of our intellectual property assets. Upon acceleration of the Credit Agreement, we would be required to repay outstanding amounts immediately or to attempt to reverse the declaration through negotiation or litigation. In addition, if an acceleration event were to occur under the Credit Agreement and not be cured, the trustee or the holders of the 2026 Notes would have the right to accelerate our repayment obligations for all principal and accrued and unpaid interest on the 2026 Notes then outstanding. If we are unable to repay amounts outstanding under the 2026 Notes and Credit Agreement, we could be forced into bankruptcy or liquidation and we would lose title to substantially all of our assets, including our intellectual property. In any related proceeding, the lenders' right to repayment under the Credit Agreement would be senior to the right of repayment of the holders of the 2026 Notes and the rights of both would be senior to the rights of the holders of our common stock. Any event of default could accordingly have a material adverse effect on our operations, financial condition and liquidity, and could cause the price of our 2026 Notes and common stock to decline significantly.

**In addition to our Credit Agreement, our other indebtedness and liabilities and any future indebtedness 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, 2024, we had \$97.2 million total aggregate principal amount of our 2026 Notes outstanding, \$67.1 million total aggregate principal amount outstanding under the Initial Term Loan, and we had approximately \$2.0 million of outstanding finance lease obligations. We may incur additional indebtedness to meet future financing needs. As described above, our Credit Agreement places restrictions on our operating and financial flexibility, and our other existing and future indebtedness could also 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 2026 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 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 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 further 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.

**Failure to obtain and maintain regulatory approval in the U.S. or in foreign jurisdictions would prevent us from commercializing and marketing our product 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. Based on the decision and on subsequent interactions with FDA, we proposed a statistical analysis plan to assess data from our pivotal clinical trial, existing data from an historical control population available from an external source and data from the narsoplimab expanded access program. The primary endpoint under the analysis plan is patient survival in our pivotal narsoplimab trial compared to that in an external registry of TA-TMA patients who were not treated with narsoplimab. Analyses similar to the primary analysis comparing survival in TA-TMA patients treated with narsoplimab under a global EAP to that of similarly at-risk TA-TMA registry patients were also included in the analysis plan, along with sensitivity analyses related to each of the primary and EAP comparisons. All statistical analyses were conducted by an independent statistical group. These data and analyses are included in our recently resubmitted BLA for narsoplimab in TA-TMA. We expect also to include these data and analyses in the MAA for narsoplimab in this indication.

We cannot guarantee when or if FDA or EMA will approve narsoplimab for the treatment of TA-TMA. Even if our clinical data, data from our EAP and statistical analyses comparing these data to an external registry of TA-TMA patients provide favorable evidence of the effectiveness of narsoplimab in the treatment of TA-TMA, the reviewing agency may determine that such evidence is insufficient to support regulatory approval for any reason, including unfavorable interpretation of our analysis results, potential differences between the diagnostic criteria used in our pivotal trial and in the external registry, a determination by the reviewing agency that the registry used in our statistical analysis is insufficiently representative of TA-TMA patients to provide a reliable control, FDA’s assessment of the comparability of the registry to the population in our pivotal trial, the sufficiency of our sensitivity analyses, and/or the lack of additional control sources. Additionally, we do not currently have narsoplimab manufacturing slots scheduled with our contract manufacturing partner and, if a pre-licensing inspection is requested in connection with agency review of our BLA or MAA, we may face difficulty in securing manufacturing capacity to support such inspection at reasonable cost, or at all, our manufacturing partner may also fail to provide other needed regulatory support on a timely basis, or at all. Any difficulties associated with our contract manufacturer’s support in connection with regulatory processes could prevent or delay review and approval of our marketing application. Overall, the requirements for resubmission of our BLA have been and may continue to be costly, require significant time and may not result in approval. Ultimately, we cannot guarantee that FDA or EMA 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 product 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 product 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. We retain the right to receive all royalties payable by Rayner on any net sales of OMIDRIA outside the U.S. as well as royalties on global net sales of OMIDRIA payable from and after December 31, 2031. We received \$115.5 million 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, product candidates, or in preparation for potential commercialization of our product candidates; and
- whether we are able to obtain marketing approval for any of our product 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.

**Significant changes to the size, structure, powers and operations of the U.S. federal government, as well as recent policy actions by the U.S. federal government, may cause economic disruptions that could, in turn, adversely impact our business, results of operations and financial conditions.**

The new administration has begun to implement significant changes to the size and scope of the federal government to achieve stated goals including reducing the federal budget deficit and national debt, improving the efficiency of government operations, and promoting innovation and economic growth. To date, these efforts have been carried out through a mix of executive actions aimed at eliminating or modifying federal agency and federal program funding, reducing the size of the federal workforce, reducing or altering the scope of activities conducted by, and possibly eliminating, various federal agencies and bureaus. If implemented, these changes may have varied effects on the economy that are difficult to predict. For instance, the delivery of government services and the distribution of federal program funds and benefits may be disrupted or, in some cases, eliminated as a result of funding cuts, recasting of federal agency mandates or a substantial reduction of the federal workforce. We rely on the availability, predictability and efficiency of federal agencies including FDA, NIDA and others in connection with the operation of our business and programs. Our business, financial condition and results of operations could be materially and adversely affected by disruptions affecting these or other agencies in areas relevant to our programs and operations.

In addition, recent policy actions by the new U.S. administration, including the imposition of new tariffs on imported materials and goods from certain foreign countries, including Canada, Mexico and China, and the temporary freeze on federal grants and loans, may have an adverse impact on our business. Increased tariffs on critical raw materials, components, and finished goods could raise our production costs, disrupt our supply chain, and reduce our competitiveness in the marketplace. Additionally, the administration's halt on certain federal research grants may negatively impact our industry. Any prolonged reductions in such funding could slow innovation, delay collaborations, and limit the adoption of new technologies that contribute to our business growth. If these or similar policy changes continue or expand, we may face increased costs. Although we cannot predict the full extent of these impacts, any prolonged disruption could adversely affect our business, financial condition, and results of operations.

**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 product 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 product 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 product 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 product 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 product 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 product 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 cGMP, 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, including as a result of the new U.S. administration.**

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product 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 product candidates. We cannot be sure whether additional legislative changes, including as a result of the U.S. administration, 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 product candidates, if any, may be.

**We have no internal capacity to manufacture commercial or clinical supplies of our product 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 product 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 product candidates that are needed for clinical trials and to support NDAs, BLAs, or similar applications to regulatory authorities seeking marketing approval for our product candidates, as well as to produce inventory of our product 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 product 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, zaltenibart and OMS1029 are biologic drug products and other product 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 product 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 product 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 product 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 product candidates may not be available on commercially reasonable terms, or at all, which may adversely affect the development and commercialization of our product 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 product 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 product 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 product 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 product candidates.

**If our clinical trials or clinical protocols are delayed, suspended or terminated, we may be unable to develop our product 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 product 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 zaltenibart, 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 product candidate, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol or to follow GCP or other study requirements, an unacceptable study design or other problems;
- adverse findings in clinical or nonclinical studies related to the safety of our product candidates in humans;
- an insufficient supply of product candidate materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product 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 zaltenibart, 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 product 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 product 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 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 product 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 product candidates and development programs, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product 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 product 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 product 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 product 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 product 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 product 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 product candidate. Many pharmaceutical and biological product

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 product 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 product 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 product candidates, the development of our product candidates, our ability to obtain regulatory approval for our product 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product candidate for follow-on indications.

We also may rely on trade secrets to protect our technologies or product 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.

**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. Demopoulos, 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 product 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 product 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 product 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 product 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 not required to comply with the auditor attestation requirements of the Sarbanes-Oxley Act.**

We are a non-accelerated filer under the Exchange Act and, therefore, we are not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. Therefore, our internal control 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.

## **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, 2024, the closing price of our stock ranged from as high as \$12.15 per share and as low as \$2.88 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 16.7 million shares of common stock were subject to outstanding options as of December 31, 2024 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, 2024, we also had approximately 6.9 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 2026 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 2026 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 2026 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. Furthermore, we are prohibited from making cash dividend payments under the terms of our secured credit facility. Therefore, we have no intention of 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 variety 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 111,926 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 6,111 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 \$6.9 million for 2025, \$7.1 million for 2026, and \$6.1 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 25, 2025, there were approximately 58,063,901 shares of our common stock outstanding, which were held by 79 holders of record.

#### **Dividends**

We have never declared or paid any cash dividends on our capital stock, and we are precluded from paying cash dividends under the terms of our secured credit facility. 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, 2024.

#### **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, 2019 and ending December 31, 2024. This graph assumes that \$100 was invested on December 31, 2019 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.

## 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 first-in-class 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 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. We

are focused on development of therapeutics to treat diseases associated with the lectin and/or alternative pathways of complement. We are developing antibodies as well as small-molecule inhibitors of key enzymes known to be centrally involved in the 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. We are 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 product candidate in our pipeline of complement-targeted therapeutics is narsoplimab (OMS721), a proprietary, patented human monoclonal antibody targeting MASP-2, the key activator 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, our long-acting antibody targeting MASP-2 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 zaltenibart (OMS906), a proprietary, patented monoclonal antibody targeting MASP-3, the key activator of the alternative pathway of complement. We believe zaltenibart has the potential to treat a wide range of alternative pathway-related diseases and that its attributes favorably differentiate zaltenibart from other marketed and in-development alternative pathway inhibitors.

Clinical development of zaltenibart is currently focused on PNH and C3G. We have initiated our Phase 3 clinical development program for zaltenibart in PNH and have an ongoing Phase 2 clinical trial evaluating zaltenibart in C3G. 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”). With NIDA funding, we successfully completed preclinical cocaine interaction/toxicology studies to assess safety of the OMS527 compound when co-administered with cocaine. Based on the successful outcome of the preclinical studies, we have initiated, and NIDA has confirmed availability of grant funding for, an in-patient, placebo-controlled clinical study evaluating the safety and effectiveness of OMS527 in adults with CUD who receive concurrent intravenous cocaine. 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*”.

#### *Preclinical Programs - Oncology Platform*

We are developing a portfolio of signaling-driven immunomodulators, oncotoxins, and an adoptive T-cell technology combined with an immunostimulator that, unlike other cellular therapy approaches requires no cellular engineering, may reduce manufacturing costs and timelines, and may maintain an enhanced anti-cancer immune response through subsequent repetitive and simple therapeutic administrations.

Our oncology development program is operating in stealth mode as we continue to confirm our results and to generate new data which we expect will contribute to our intellectual property position. For more information, see Part I, Item 1 in this Annual Report on Form 10-K under the heading “Preclinical Programs and Platforms: *Oncology Platform*”.

## *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 lens 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, to Rayner. Rayner paid us \$126.0 million at the closing and we retained all outstanding accounts receivable, accounts payable and accrued expenses as of the closing date.

As contemplated by the Asset Purchase Agreement, in December 2022, we earned a \$200.0 million Milestone Payment upon the establishment of separate payment for OMIDRIA for a continuous period of at least four years when furnished in the ASC setting. We received \$200.0 million in February 2023. Upon achieving the Milestone Event, the royalty rate applicable to U.S. net sales of OMIDRIA was reduced from 50% to 30%. The 30% royalty rate continues 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 separate payment (i.e., becomes included in the packaged payment rate for the surgical procedure) under Medicare Part B, or in certain circumstances involving entry of generic competition for OMIDRIA, the U.S. base royalty rate would be further 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, we recorded an OMIDRIA contract royalty asset on our balance sheet. The results of OMIDRIA activities are classified as discontinued operations in our consolidated statements of operations and comprehensive income (loss) and excluded from continuing operations for all periods presented. 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.

On September 30, 2022, we sold to DRI an interest in a portion of our future OMIDRIA royalty receipts for \$125.0 million which we recorded as an OMIDRIA royalty obligation on our consolidated balance sheet. DRI was entitled under that arrangement to receive royalties on OMIDRIA net sales between September 1, 2022 and December 31, 2030, subject to certain annual caps.

On February 1, 2024, we sold an expanded interest in our future OMIDRIA royalties to DRI and received \$115.5 million in cash consideration, which we recorded as an addition to the OMIDRIA royalty obligation. The amended and restated royalty purchase agreement with DRI (the “Amendment”) eliminated the previously existing annual caps on royalty payments after January 1, 2024, and provides that DRI receives all royalties on U.S. net sales of OMIDRIA payable between January 1, 2024 and December 31, 2031. In addition to the cash consideration received at closing, the Amendment also entitles us 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. All royalties earned on OMIDRIA sales within the U.S. through December 31, 2031 are remitted by Rayner to an escrow account established by Omeros, from which payments are made to DRI. We retain the rights to receive all royalties payable by Rayner on any net sales of OMIDRIA outside the U.S. as well as royalties on global net sales of OMIDRIA payable from and after December 31, 2031, including royalties on U.S. OMIDRIA net sales. To date, international royalties have not been significant. DRI has no recourse to our assets other than its interest in OMIDRIA royalties. Interest expense on the OMIDRIA royalty obligation is recorded as a component of continuing operations. 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.

## *Payment on Maturity of 2023 Notes*

On November 15, 2023, we extinguished \$95.0 million of our 6.25% convertible senior notes (the “2023 Notes”) at par upon maturity.

## *2024 Term Loan and Repurchase of 2026 Notes*

In December 2023, we repurchased \$9.1 million par value of our 2026 Notes on the open market at approximately 55% of par value, realizing a \$4.1 million non-cash gain on extinguishment.

On June 3, 2024 (the “Closing Date”), we, with certain subsidiaries, as guarantors, entered into the Credit Agreement with Athyrium and Highbridge as lenders (together with additional lenders from time to time, the “Lenders”) and Wilmington Savings Fund Society, FSB, as administrative agent and collateral agent. The Credit Agreement provides for a senior secured term loan facility initially of up to \$92.1 million consisting of (i) the Initial Term Loan of \$67.1 million, which was fully funded on the Closing Date, and (ii) a \$25.0 million Delayed Draw Term Loan, which may be drawn once in full upon notice delivered on or prior to June 3, 2025, conditioned on receipt of FDA approval of narsoplimab in TA-TMA within 30 days of the notice. We do not expect that FDA



approval of narsoplimab will be obtained within a timeframe that would permit the Delayed Draw Term Loan to be drawn absent an amendment to, or waiver of, this condition. Proceeds of the Delayed Draw Term Loan, if borrowed, must be used to fund the commercialization of narsoplimab and to pay transaction costs associated with the Delayed Draw Term Loan. The Initial Term Loan has no original issue discount, while the Delayed Draw Term Loan, if drawn, would be issued with an original issue discount of 3.00%.

In 2024, we used the \$67.1 million Initial Term Loan, along with \$21.7 million of cash on hand to repurchase from the Lenders \$118.1 million aggregate principal amount of the 2026 Notes (the “2026 Note Repurchase Transaction”). The principal amount retired in the 2026 Note Repurchase Transaction represented a 55% reduction of the outstanding principal balance of the 2026 Notes at a purchase price of approximately 75% of par value.

We are permitted under the Credit Agreement to repurchase additional outstanding 2026 Notes for cash in open market or privately negotiated transactions, subject to certain limitations described below. Additionally, until the earlier of November 1, 2025 and the date we elect to draw under the Delayed Draw Term Loan, we, at our sole discretion, may exchange up to \$14.9 million aggregate principal amount of outstanding 2026 Notes for cash and additional term loan amounts, with the holders of such notes becoming Lenders under the Credit Agreement (any such additional term loans, together with the Initial Term Loan and the Delayed Draw Term Loan, the “Loans”). We also retain all potential future value of the capped call purchased in connection with the issuance of the 2026 Notes covering all shares underlying the original 2026 Notes.

All indebtedness outstanding under the Credit Agreement is guaranteed by certain of our direct and indirect subsidiaries, other than certain foreign subsidiaries that are not material (we and the guarantors, collectively, the “Credit Parties”). Pursuant to a Pledge and Security Agreement, dated June 3, 2024, the indebtedness under the Credit Agreement is secured by a first-priority security interest in and lien on substantially all tangible and intangible property of the Credit Parties, subject to customary exceptions, and excluding royalty interests in OMIDRIA and certain related rights.

The Credit Agreement contains certain customary default provisions, representations and warranties and affirmative and negative covenants, including a covenant for the Credit Parties to maintain at all times unrestricted cash, cash equivalents and short-term investments of at least \$25.0 million in accounts subject to control agreements, and a covenant limiting the use of cash for open market or privately negotiated repurchases of any outstanding 2026 Notes to: (i) an initial amount not exceeding \$25.0 million, which may be increased by up to an additional \$10.0 million subject to the satisfaction of certain conditions; (ii) an unlimited amount, if the amount of Loans outstanding at the time of repurchase does not exceed \$38.5 million; and (iii) an additional amount not to exceed 50% of the net cash proceeds from an equity offering, provided that we offer to prepay an equal amount of Loans with the net cash proceeds of such offering.

The Loans accrue interest at an adjusted term secured overnight financing rate, (“adjusted term SOFR”) (with a 3.00% floor) plus 8.75% per annum, payable quarterly. We may choose to pay up to 50% of any quarterly interest payment in kind by adding the portion of such interest payment to the outstanding principal amount of Loans using a quarterly interest rate of adjusted term SOFR (with a 3.00% floor) plus 10.25% per annum. A default interest rate of an additional 3.00% per annum would apply on all outstanding obligations after the occurrence and during the continuance of certain specified events of default.

The Credit Agreement with a four-year term has a scheduled maturity date of June 3, 2028 (unless all Loans become due and payable at an earlier date, whether by acceleration or otherwise). If on November 1, 2025, (i) the aggregate principal amount of the 2026 Notes outstanding that is not held by the Lenders is equal to or greater than \$38.5 million and (ii) we have not made nor delivered notice that we expect to make certain voluntary or mandatory prepayments under the Credit Agreement of at least \$20.0 million in the aggregate, then we would be required to prepay the Loans in the amount necessary to achieve the \$20.0 million prepayment requirement. We expect to prepay the \$20.0 million in November 2025 along with a \$1.0 million prepayment penalty and have reflected this consideration in our consolidated balance sheet. All mandatory prepayments are subject to the prepayment premiums as described below.

We may elect to prepay Loans, in whole or in part, in cash, subject to (i) during the first year of such Loans, a make-whole premium plus 5.00% of the aggregate principal amount of Loans subject to prepayment (unless the prepayment is made in contemplation of a change of control, in which case only the make-whole premium would be payable); (ii) during the second year, a 5.00% prepayment premium; and (iii) during the third year, a 3.00% prepayment premium. The Credit Agreement requires mandatory prepayments of Loans in an amount equal to 60% of the net cash proceeds (excluding research and development and certain other milestone payments) received by the Credit Parties from asset sales and licenses, provided that if an asset sale or license involving narsoplimab occurs while any Delayed Draw Term Loans are outstanding, mandatory prepayments must be in an amount equal to 100% of the net cash proceeds from such sale. Mandatory prepayments are also required: (i) from insurance recoveries on loss of property that are not otherwise reinvested in other assets of the Credit Parties; (ii) from indebtedness incurred by any of the Credit Parties other than as permitted by the Credit Agreement; (iii) in the event of a change of control and (iv) in respect of 25% of the amount of any Milestone Payment received from DRI its affiliates on the basis of net sales of OMIDRIA.



## Financial Summary

As of December 31, 2024, we had cash, cash equivalents and short-term investments of \$90.1 million available to fund operations and to service debt.

## 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 product candidate, CROs, clinical trial sites, collaborators, licensors and consultants. Preclinical 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. Our accounting policy is to expense all manufacturing costs related to product candidates until regulatory approval is reasonably assured in either the U.S. or European Union.

The following table illustrates our expenses associated with these activities:

	Year Ended Year Ended December 31,		
	2024	2023	2022
	(In thousands)		
Research and development expenses:			
Direct external expenses:			
Clinical research and development:			
MASP-2 program - OMS721 (narsoplimab)	\$ 35,913	\$ 35,352	\$ 50,408
MASP-3 program - OMS906 (zaltenibart)	24,997	22,853	6,304
MASP-2 program - OMS1029	4,059	6,249	2,687
Other	115	153	442
Total clinical research and development	65,084	64,607	59,841
Preclinical research and development	6,465	5,172	7,254
Total direct external expenses	71,549	69,779	67,095
Internal, overhead and other expenses	43,841	40,337	39,503
Stock-based compensation expenses	4,133	4,754	6,123
Total research and development expenses	<u>\$ 119,523</u>	<u>\$ 114,870</u>	<u>\$ 112,721</u>

Clinical research and development expenses increased \$0.5 million between 2024 and 2023. The change primarily relates to \$16.1 million of TA-TMA drug manufacturing costs in anticipation of our BLA and \$2.1 million in zaltenibart clinical trials expense and associated costs to manufacture drug supply. These costs are partially offset by a \$15.5 million reduction in IgA nephropathy expenses with the closing out of the program and a \$2.2 million reduction in OMS1029 expenses primarily due to the completion of one of our single ascending dose studies.

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 in 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.

Preclinical research and development expenses increased \$1.3 million in 2024 compared to 2023, primarily due to increased preclinical oncology research and cocaine addiction work during 2024. The cocaine addiction work is being funded by a grant from NIDA, with associated grant revenue included in other income. The \$2.1 million decrease in 2023 over 2022 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, offset by an increase in preclinical oncology work during 2023.

Internal overhead and other expenses increased \$3.5 million for the year ended December 31, 2024 primarily due to additional employee related costs and having received an employee retention tax credit in the prior year that was recorded as an offset to expense.

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

We expect our overall research and development costs in 2025 to be slightly higher than in 2024, driven by increases in zaltenibart clinical trial costs associated with Phase 3 trials in PNH and C3G, a milestone payment under an existing licensing agreement, and drug manufacturing costs, which we expect to be partially offset by decreases in narsoplimab drug manufacturing and clinical trial costs. Our accounting policy is to expense all manufacturing costs related to product 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 product 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 product candidate as well as ongoing assessments of each program's commercial potential. In addition, we cannot forecast with precision which product 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 product 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 marketing and administrative personnel who are not directly engaged in research and development. Costs also include marketing expenses, professional and legal services, general corporate costs and an allocation of our occupancy costs.

	Year Ended December 31,		
	2024	2023	2022
	(In thousands)		
Selling, general and administrative expenses:			
Selling, general and administrative expenses, excluding stock-based compensation expense	\$ 43,375	\$ 42,520	\$ 42,626
Stock-based compensation expense	6,360	7,140	8,042
Total selling, general and administrative expenses	<u>\$ 49,735</u>	<u>\$ 49,660</u>	<u>\$ 50,668</u>

The changes in stock-based compensation expense between the three covered years were due to the valuation and timing of vesting related to employee stock options.

Our selling, general and administrative expenses are expected to be higher than in 2024. The magnitude of the anticipated increase in selling, general and administrative expenses for 2025 will be highly dependent on whether narsoplimab receives U.S. regulatory approval for treatment of TA-TMA. If narsoplimab is approved in 2025, we expect to hire a field sales force and initiate commercial launch activities which will increase our selling, general and administrative expenses.

#### *Interest Expense*

Interest expense is comprised of contractual cash and accrued interest on our 2026 Notes, 2023 Notes and Initial Term Loan. In addition, we record pass through interest on the OMIDRIA royalty obligation, non-cash interest comprised of remeasurement adjustments taken on our OMIDRIA royalty obligation and amortization of debt discount or premiums on our notes and term debt.

Interest expense, net of premiums, discounts, issuance costs and remeasurement adjustments is shown below:

	Year Ended December 31,		
	2024	2023	2022
	(In thousands)		
2023 Notes			
Contractual interest expense	\$ —	\$ 5,195	\$ 5,938
Amortization of debt discount and issuance costs	—	619	662
Interest expense on 2023 Notes	—	5,814	6,600
2026 Notes			
Contractual interest expense	7,772	11,774	11,814
Amortization of debt discount and issuance costs	859	1,234	1,167
Interest expense on 2026 Notes	8,631	13,008	12,981
OMIDRIA royalty obligation			
Pass through interest remitted to administrative agent	20,634	11,848	1,253
Non-cash remeasurement adjustment	(5,614)	—	1,695
Interest expense on OMIDRIA royalty obligation	15,020	11,848	2,948
2024 Initial Term Loan			
Contractual interest expense	5,525	—	—
Amortization of debt premium and issuance costs	(4,681)	—	—
Interest expense on 2024 Initial Term Loan	844	—	—
Finance leases and other			
	180	174	173
Total interest expense	\$ 24,675	\$ 30,844	\$ 22,702

Interest expense decreased \$6.2 million in 2024 compared to 2023 primarily due to extinguishing \$95.0 million in par value of our 2023 Notes at maturity in November 2023 and partially repurchasing \$127.2 million in collective par value of our 2026 Notes in December 2023 and June 2024 reducing interest expense on our 2026 Notes by \$4.4 million. This decrease was partially offset by increased interest expense of \$3.2 million related to our OMIDRIA royalty obligation as we added \$115.5 million of principal upon sale in February 2024 to DRI of our remaining OMIDRIA U.S. royalty earnings through 2031. In addition, with the execution of the Credit Agreement, we incurred \$0.8 million in effective interest on our Initial Term Loan with Highbridge and Athrium.

Interest expense increased \$8.1 million in 2023 compared to 2022 primarily due to interest incurred from our OMIDRIA royalty obligation.

Contractual interest expense is comprised of cash interest paid during the year and the net change in accrued interest. Interest on our OMIDRIA royalty obligation is calculated under the effective interest method and represents a portion of the royalties remitted by Rayner to our administrative agent, Wilmington Savings Fund Society, FSB, along with principal. Pass through interest paid to DRI is offset by non-cash remeasurement adjustments taken to properly reflect the OMIDRIA royalty obligation for changes in probable cash flows on our future expected Rayner royalties. Debt discounts on the 2026 Notes and 2023 Notes are accretive whereas the unrealized gain on the 2026 Note Repurchase Transaction is treated as a premium on the Initial Term Loan and deducted from contractual interest expense.

For further information see Part II, Item 8, “Note 6 – Debt” and “Note 8 – OMIDRIA Royalty Obligation” to our Consolidated Financial Statements in this Annual Report on Form 10-K.

## Interest and Other Income

	Year Ended December 31,		
	2024	2023	2022
	(In thousands)		
Interest and other income	\$ 11,304	\$ 16,342	\$ 4,062

Interest and other income principally includes \$8.4 million of interest earned on our investments, \$1.6 million earned on sublease rental income and \$1.3 million of NIDA grant income. The \$5.0 million decrease in interest and other income between 2024 and 2023 was primarily due to holding lower average cash and investment balances than in the prior year. The \$12.3 million increase in interest and other income between 2023 and 2022 was a result of receiving the \$200.0 million Milestone Payment from Rayner in February 2023 and investing those funds.

We expect interest and other income in 2025 to be less than 2024 primarily due to lower average cash and investment balances during 2025.

## Gain on Early Extinguishment of Convertible Senior Notes

	Year Ended December 31,		
	2024	2023	2022
	(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 classified as discontinued operations for all periods presented.

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

	Year Ended December 31,		
	2024	2023	2022
	(In thousands)		
Interest on OMIDRIA contract royalty asset	\$ 16,922	\$ 15,315	\$ 18,634
Remeasurement adjustments	7,969	41,167	14,457
Other income	1,211	1,087	307
Milestone income	—	—	200,000
Income before income tax	26,102	57,569	233,398
Income tax expense <sup>(1)</sup>	(288)	(462)	(3,952)
Net income from discontinued operations, net of tax	\$ 25,814	\$ 57,107	\$ 229,446

(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.

## Interest on OMIDRIA contract royalty asset

During the years ended December 31, 2024, 2023 and 2022, we recorded \$16.9 million, \$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 effective interest rate of 11.0%.

### Remeasurement Adjustments

During the years ended December 31, 2024, 2023 and 2022, we recorded remeasurement adjustments of \$8.0 million, \$41.2 million and \$14.5 million, respectively. Periodically, but at least annually, we remeasure the OMIDRIA contract royalty asset when there is a greater probability of achieving materially higher or lower royalty earnings than previously expected. To measure the OMIDRIA contract royalty asset, we use 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. Remeasurement is impacted by any changes to the probability-weighting applied to the range of potential outcomes that could occur. 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.

### Income Tax Expense

For the years ended December 31, 2024, 2023 and 2022, we recorded state income tax expense of \$0.3 million, \$0.5 million and \$4.0 million, respectively, in discontinued operations.

## **Financial Condition - Liquidity and Capital Resources**

As of December 31, 2024, we had cash, cash equivalents and short-term investments of \$90.1 million. Our cash used in operations for the year ended December 31, 2024 was \$148.8 million and included a net loss for the year of \$156.8 million. Pursuant to a covenant in the Credit Agreement, we must maintain \$25.0 million of unrestricted cash, cash equivalents and short-term investments at all times.

In recent years, we have incurred net losses from continuing operations and negative cash flows from operations. The recurring losses, in combination with our cash and investment balances as of December 31, 2024, expected repayment of a portion of the borrowings under our secured credit facility on or prior to November 1, 2025 and maturity of our 2026 Notes on February 15, 2026, raise substantial doubt about our ability to continue as a going concern through one year from the issuance of the Company's consolidated financial statements. As we currently do not have an ongoing source of revenue sufficient to cover our operating costs, we will need to raise additional capital to accomplish our business plan. 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 amount up to \$150.0 million. Our Delayed Draw Term Loan of \$25.0 million may be drawn once in full upon notice delivered on or prior to June 3, 2025, conditioned on receipt of FDA approval of narsoplimab in TA-TMA within 30 days of the notice; however, we do not expect that FDA approval of narsoplimab will be obtained within the timeframe that would permit us to draw the Delayed Draw Term Loan absent an amendment to, or a waiver of, this condition. Proceeds of the Delayed Draw Term Loan, if available, may only be used towards any related transaction costs and for commercialization of narsoplimab efforts of TA-TMA.

We have had preliminary discussions with certain holders of the 2026 Notes regarding a potential refinancing of the 2026 Notes and we may pursue additional debt financings to retire the 2026 Notes that remain outstanding and to raise additional capital to fund operations. Should it be necessary or determined to be strategically advantageous, we also could pursue public and private offerings of our equity securities, additional debt transactions or restructurings, future royalty sales, or other strategic transactions, which may include licensing or selling a portion or all of one or more of our existing technologies. However, pursuing debt financings, certain equity offerings or other strategic transactions may result in mandatory prepayments of the Initial Term Loan. See Part II, Item 8, “Note 6 – Debt” to our Consolidated Financial Statements in this Annual Report on Form 10-K for additional information.

If these capital resources, for any reason, are needed but inaccessible, it would have a significant negative impact on our financial condition. For purposes of determining available capital resources, potential future royalty and/or milestone receipts are excluded. Should it be necessary, we plan to manage our operating expenses and 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,		
2024	2023	2022
(In thousands)		

### Selected cash flow data

Cash provided by (used in):

Operating activities	\$ (148,803)	\$ 74,726	\$ (86,483)
Investing activities	\$ 82,217	\$ 27,454	\$ (127,564)
Financing activities	\$ 62,881	\$ (106,084)	\$ 124,248

*Operating Activities.* Net cash used in operating activities for the year ended December 31, 2024 decreased by \$223.5 million compared to the same period in 2023. This decrease was primarily due to collecting the \$200.0 million Milestone Payment from Rayner in the prior year and a \$15.5 million decrease in accounts payable and accrued expenses in the current year.

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 \$200.0 million Milestone Payment from Rayner in February 2023 and a \$15.3 million increase in accounts payable and accrued expenses in 2023. This increase was partially 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.

*Investing Activities.* Net cash provided by investing activities for the year ended December 31, 2024 increased \$54.8 million as compared to the same period in 2023. Significant initial investment purchases during the periods were the investment of the \$200.0 million Milestone Payment we received from Rayner in February 2023 and the \$115.5 million we received from DRI in February 2024 related to the sale of future OMIDRIA royalties.

Net cash provided by investing activities increased \$155.0 million during 2023 compared to 2022 driven by collection of the \$200.0 million Milestone Payment from Rayner we received in February 2023.

*Financing Activities.* Net cash provided by financing activities increased \$169.0 million during 2024 compared to the prior year. The increase was primarily due to receiving \$115.5 million in cash from DRI related to the sale of future OMIDRIA royalties and extinguishing \$95.0 million of par value on our 2023 Notes in the prior year. This was partially offset by increased payments to DRI of \$17.6 million in 2024 related to the OMIDRIA royalty obligation, an additional \$16.9 million paid to repurchase our 2026 Notes and increased common stock repurchases of \$7.2 million.

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 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.

### Contractual Obligations and Commitments

#### *Operating and Finance Leases*

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. As of December 31, 2024, the remaining aggregate non-cancelable rent payable under the initial term of the lease, excluding common area maintenance and related operating expenses, was \$20.2 million.

We have finance leases for certain laboratory and office equipment that have lease terms expiring through October 2029. As of December 31, 2024, the remaining aggregate non-cancellable finance lease payable was \$2.2 million.

#### *Debt*

For more information regarding the convertible senior notes extinguished in mid-November 2023, convertible senior notes due in February 2026 and our Credit Agreement, see Part II, Item 8, "Note 6 - Debt".

## *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-cancellable obligations under other agreements for the acquisitions of goods and services associated with the manufacturing of our product candidates, which contain firm commitments. As of December 31, 2024, our aggregate firm commitments were \$4.7 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:

- OMIDRIA royalties and contract asset accounting;
- OMIDRIA royalty obligation accounting; and
- accounting for debt issuances, primarily related to fair valuing debt and issuance costs.

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.

## *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 Milestone Event triggering the \$200.0 million Milestone Payment in 2022. 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 \$15.3 million change in value of the OMIDRIA contract royalty asset, resulting in a potential OMIDRIA contract royalty asset valued within the range of \$138.0 million to \$168.7 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 reports of 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 implied 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, 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. Our estimate of cash flows from future royalties is derived from the contract royalty asset accounting described above.

#### *Debt Issuances*

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 first evaluated as to whether they qualify as a troubled debt restructuring (“TDR”) under ASC Topic 470-60, *Debt - Troubled Debt Restructuring by Debtors* (“ASC 470-60”). ASC 470-60 requires debt modifications to be evaluated if (1) the borrower is experiencing financial difficulty, and (2) the lender grants the borrower a concession. If both conditions are met under TDR accounting, we would record as the carrying value of the new debt any repurchased old debt less any cash paid. No gain on restructuring is recognized unless the carrying value of the new debt exceeds the undiscounted cash flows of the new debt. Any cancellation of debt income is amortized over the term of the new debt. We determined that the Initial Term Loan qualified as a TDR. Therefore, we amortized as debt premium the cancellation of debt income from the partial repurchase of the 2026 Notes against the Initial Term Loan. If a TDR is determined to not have occurred, we evaluate the modification in accordance with ASC Topic 470-50-40, *Debt - Modifications and Extinguishments*, which requires modification of debt instruments to be evaluated to assess whether the modifications are considered “substantial”. In instances where our future cash flows change more than 10%, we record our debt at fair value based on factors available to us for similar borrowings and use the extinguishment accounting method. We extinguished the 2023 Notes at maturity. The partial repurchase of the 2026 Notes in 2023 was deemed to be a modification whereby we were able to recognize a \$4.1 million gain on debt extinguishment.

#### **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, 2024, we had cash, cash equivalents and short-term investments of \$90.1 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. The money market funds in our investment portfolio are not leveraged and are classified as available-for-sale. 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, we are not exposed to significant loss due to changes in interest rates.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

### **Index to Consolidated Financial Statements**

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## **Report of Independent Registered Public Accounting Firm**

To the Shareholders and the Board of Directors of Omeros Corporation

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Omeros Corporation (the Company) as of December 31, 2024 and 2023, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

### **The Company's Ability to Continue as a Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **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 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 accounts or disclosures to which it relates.



## ***OMIDRIA Contract Royalty Asset***

<i>Description of the Matter</i>	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 of expected royalty payments is complex and requires judgment due to the level of estimation uncertainty and the sensitivity of the asset's value to changes in forecast 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 of future market and regulatory conditions.
<i>How We Addressed the Matter in Our Audit</i>	<p>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 probability weighting of those scenarios.</p> <p>To evaluate the appropriateness and likelihood of occurrence of the estimated future royalties in various scenarios and probability weighting included in management's calculation, we considered historical results of the Company's business and third-party data. We verified the clerical accuracy of the contract royalty asset calculation and agreed it to royalty rates in the asset purchase agreement. We also evaluated the Company's disclosures in the consolidated financial statements related to these matters.</p>

/s/Ernst & Young LLP

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

Seattle, Washington

March 31, 2025

**OMEROS CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share and per share data)

	<u>December 31,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,400	\$ 7,105
Short-term investments	86,732	164,743
OMIDRIA contract royalty asset	29,083	29,373
Receivables	7,739	8,096
Prepaid expense and other assets	7,166	8,581
Total current assets	134,120	217,898
OMIDRIA contract royalty asset, non-current	124,266	138,736
Right of use assets	14,961	18,631
Property and equipment, net	2,678	1,950
Restricted investments	1,054	1,054
<b>Total assets</b>	<u>\$ 277,079</u>	<u>\$ 378,269</u>
<b>Liabilities and shareholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 5,905	\$ 7,712
Accrued expenses	26,005	31,868
OMIDRIA royalty obligation	20,645	8,576
Term debt	21,000	—
Lease liabilities	5,971	5,160
Total current liabilities	79,526	53,316
OMIDRIA royalty obligation, non-current	195,612	116,550
Convertible senior notes, net	97,178	213,155
Term debt, non-current	69,405	—
Lease liabilities, non-current	13,466	18,143
Other accrued liabilities, non-current	4,501	2,088
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, 2024 and December 31, 2023	—	—
Common stock, par value \$0.01 per share, 150,000,000 shares authorized at December 31, 2024 and December 31, 2023; 58,044,465 and 61,128,597 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively.	580	611
Additional paid-in capital	727,156	727,936
Accumulated deficit	(910,345)	(753,530)
Total shareholders' equity (deficit)	(182,609)	(24,983)
<b>Total liabilities and shareholders' equity (deficit)</b>	<u>\$ 277,079</u>	<u>\$ 378,269</u>

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)

	<b>Year Ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
Costs and expenses:			
Research and development	\$ 119,523	\$ 114,870	\$ 112,721
Selling, general and administrative	49,735	49,660	50,668
Total costs and expenses	<u>169,258</u>	<u>164,530</u>	<u>163,389</u>
Loss from operations	(169,258)	(164,530)	(163,389)
Interest expense	(24,675)	(30,844)	(22,702)
Interest and other income	11,304	16,342	4,062
Gain on early extinguishment of convertible senior notes	—	4,112	—
Net loss from continuing operations	(182,629)	(174,920)	(182,029)
Net income from discontinued operations, net of tax	25,814	57,107	229,446
Net income (loss)	<u>\$ (156,815)</u>	<u>\$ (117,813)</u>	<u>\$ 47,417</u>
Basic and diluted net income (loss) per share:			
Net loss from continuing operations	\$ (3.14)	\$ (2.79)	\$ (2.90)
Net income from discontinued operations	0.44	0.91	3.66
Net income (loss)	<u>\$ (2.70)</u>	<u>\$ (1.88)</u>	<u>\$ 0.76</u>
Weighted-average shares used to compute basic and diluted net income (loss) per share	58,170,931	62,739,227	62,737,091

See accompanying Notes to Consolidated Financial Statements

**OMEROS CORPORATION**

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)**

(In thousands, except share data)

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-in Capital</b>	<b>Deficit</b>	<b>Shareholders' Equity/(Deficit)</b>
<b>Balance at December 31, 2021</b>	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
<b>Balance at December 31, 2022</b>	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)
<b>Balance at December 31, 2023</b>	61,128,597	611	727,936	(753,530)	(24,983)
Issuance of common stock upon exercise of stock options	111,109	1	546	—	547
Repurchases of common stock	(3,195,241)	(32)	(11,819)	—	(11,851)
Stock-based compensation	—	—	10,493	—	10,493
Net loss	—	—	—	(156,815)	(156,815)
<b>Balance at December 31, 2024</b>	58,044,465	\$ 580	\$ 727,156	\$ (910,345)	\$ (182,609)

See accompanying Notes to Consolidated Financial Statements

**OMEROS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Year Ended December 31,		
	2024	2023	2022
<b>Operating activities:</b>			
Net income (loss)	\$ (156,815)	\$ (117,813)	\$ 47,417
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Stock-based compensation expense	10,493	11,650	14,072
Depreciation and amortization	950	920	952
Amortization of discount and issuance costs on convertible notes	859	1,853	1,830
Amortization of non-cash interest and issuance costs on term debt	844	—	—
Non-cash interest on OMIDRIA contract royalty asset	(16,922)	(15,315)	(18,634)
Remeasurement on OMIDRIA contract royalty asset	(7,969)	(41,167)	(14,457)
Non-cash interest remeasurement on the OMIDRIA royalty obligation	(5,614)	—	1,695
Accretion on U.S. government treasury bills, net	(4,371)	(8,714)	—
Gain on early extinguishment of convertible senior notes	—	(4,112)	—
Changes in operating assets and liabilities:			
OMIDRIA contract royalty asset	39,651	40,595	65,439
Prepaid expenses and other	517	(2,978)	934
Receivables	357	205,125	(175,066)
Accounts payable and accrued expense	(10,783)	4,682	(10,665)
Net cash provided by (used in) operating activities	(148,803)	74,726	(86,483)
<b>Investing activities:</b>			
Proceeds from the sale and maturities of investments	1,069,767	1,046,482	301,594
Purchases of investments	(987,385)	(1,018,602)	(429,045)
Purchases of property and equipment	(165)	(426)	(113)
Net cash provided by (used in) investing activities	82,217	27,454	(127,564)
<b>Financing activities:</b>			
Proceeds from sale of future royalties	115,525	—	125,000
Proceeds upon exercise of stock options	547	150	415
Payment on maturity of 2023 convertible senior notes	—	(95,000)	—
Repurchase of 2026 convertible senior notes	(21,731)	(4,873)	—
Principal payments on OMIDRIA royalty obligation	(18,780)	(1,152)	(417)
Repurchases of common stock	(11,851)	(4,654)	—
Payments on finance lease obligations	(829)	(555)	(750)
Net cash provided by (used in) financing activities	62,881	(106,084)	124,248
Net decrease in cash and cash equivalents	(3,705)	(3,904)	(89,799)
Cash and cash equivalents at beginning of period	7,105	11,009	100,808
Cash and cash equivalents at end of period	\$ 3,400	\$ 7,105	\$ 11,009
<b>Supplemental cash flow information</b>			
Cash paid for interest	\$ 35,686	\$ 29,923	\$ 19,178
Equipment acquired under finance lease	\$ 1,523	\$ 952	\$ 40
Cash paid for income taxes, net	\$ 165	\$ 3,292	\$ 80

See accompanying Notes to Consolidated Financial Statements



## OMEROS CORPORATION

### 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 diseases, including complement-mediated diseases and cancers related to dysfunction of the immune system, as well as addictive and compulsive disorders.

Our clinical-stage development programs include: 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; zaltenibart, also known as 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”). We successfully completed a pivotal clinical trial for narsoplimab in TA-TMA and previously submitted to FDA a biologics license application (“BLA”) seeking marketing approval for narsoplimab in this indication. In October 2021, FDA issued a complete response letter (“CRL”) with respect to the original BLA and 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, including paths based on comparison of survival data from the completed pivotal trial versus a historical control group. Based on the recommendations included in the appeal decision and on subsequent interactions with FDA’s review division, we developed a statistical analysis plan to assess data from our pivotal clinical trial, existing data from a historical control population available from an external source and data from the narsoplimab expanded access program.

In March 2025, we resubmitted to FDA a BLA seeking regulatory approval for narsoplimab in TA-TMA. FDA has 30 days to decide whether the application is sufficiently complete to permit a review of the BLA. Assuming FDA agrees to review the BLA, we expect the resubmission to be classified as Type B, meaning that the target date for FDA action on the BLA under the Prescription Drug User Fee Act (“PDUFA”) is expected to be in September 2025. As with any BLA or new drug application, there can be no guarantee that, even if FDA agrees to review the BLA, that FDA will complete its review within a given timeframe, or that our BLA will ultimately be approved.

Our lectin pathway program also includes OMS1029, our long-acting antibody targeting MASP-2. We have completed Phase 1 clinical trials evaluating both single-ascending and multiple ascending doses of OMS1029. Results of these studies support once-quarterly dosing administered either intravenously or subcutaneously. OMS1029 has been well tolerated to date with no safety concerns identified. We are evaluating several potential indications for Phase 2 clinical development of OMS1029.

Our pipeline of clinical-stage complement-targeted therapeutic candidates also includes zaltenibart, a proprietary, patented monoclonal antibody targeting MASP-3, the key and most proximal activator of the alternative pathway of complement. We have substantially completed two Phase 2 clinical trials evaluating zaltenibart in paroxysmal nocturnal hemoglobinuria (“PNH”) and have an ongoing open label extension study to assess the long-term efficacy and safety of zaltenibart in PNH patients who have completed either of the two Phase 2 clinical trials. We have initiated our Phase 3 clinical development program for zaltenibart in this indication. We also have an ongoing program evaluating zaltenibart in C3G, a rare and debilitating renal disease driven by complement dysregulation.

Our phosphodiesterase 7 (“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 (“NIDA”), part of the National Institutes of Health, to develop, at NIDA’s request, our lead orally administered PDE7 inhibitor compound for the treatment of cocaine use disorder (“CUD”). NIDA awarded the grant to us for a total of \$6.24 million over three years, of which we have claimed and received \$1.1 million of funding to date and recognized \$1.3 million into Other Income in our consolidated statement of operations and comprehensive income (loss). The grant 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 has been completed successfully and provides the drug-interaction safety data necessary to support the human study of OMS527 in CUD. We expect enrollment in the study evaluating OMS527 in adult patients with CUD to begin in 2025, also fully funded by NIDA.

We also have various programs in preclinical research and development.

#### *OMIDRIA Sale and Royalty Monetization Transactions*

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, which we recorded as an OMIDRIA contract asset on our consolidated balance sheet. As a result of this divestiture, the results of OMIDRIA activities are classified as 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”).

On September 30, 2022, we sold an interest in a portion of our future OMIDRIA royalties to DRI Healthcare Acquisitions LP (“DRI”) and received \$125.0 million in cash consideration, which we recorded as an OMIDRIA royalty obligation on our consolidated balance sheet. Interest expense on the royalty obligation is recorded as a component of continuing operations.

On February 1, 2024, we sold an expanded interest in OMIDRIA royalties to DRI and received \$115.5 million in cash consideration, which we recorded as an addition to the OMIDRIA royalty obligation. The amended and restated royalty purchase agreement with DRI (the “Amendment”) eliminates the previously existing annual caps on royalty payments after January 1, 2024, and provides that DRI receives all royalties on U.S. net sales of OMIDRIA payable between January 1, 2024 and December 31, 2031. All royalties earned on OMIDRIA sales within the U.S. through December 31, 2031 are remitted by Rayner to an escrow account established by Omeros, from which payments are made to DRI. After December 31, 2031, we will retain any U.S. OMIDRIA royalties. We are entitled to retain all royalties on net sales of OMIDRIA outside of the United States. (See “Note 8 – OMIDRIA Royalty Obligation”).

#### *Term Loan and Repurchase of 2026 Notes*

On June 3, 2024, we, with certain subsidiaries, as guarantors, entered into a Credit and Guaranty Agreement (the “Credit Agreement”) with funds managed by Athyrium Capital Management (collectively “Athyrium”) and funds managed by Highbridge Capital Management (collectively “Highbridge”) as Lenders (the “Lenders”). The Credit Agreement provides for a senior secured term loan facility of up to \$92.1 million, consisting of an initial term loan of \$67.1 million (the “Initial Term Loan”) and a \$25.0 million delayed draw term loan (the “Delayed Draw Term Loan”), which may be drawn once in full upon notice delivered on or prior to June 3, 2025, conditioned on receipt of FDA approval of narsoplimab in TA-TMA within 30 days of the notice.

Also, we used the Initial Term Loan along with \$21.7 million in cash on hand, to repurchase from the Lenders \$118.1 million aggregate principal amount of our existing 5.25% convertible senior notes due on February 15, 2026 (the “2026 Notes” and such repurchase, the “2026 Note Repurchase Transaction”), which resulted in a \$51.0 million reduction in our outstanding debt. (See “Note 6 – Debt” for a description of the Credit Agreement provision).

#### *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 reflect all adjustments, consisting of normal recurring adjustments and non-recurring adjustments, considered necessary for the fair presentation of such information. Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”).

#### *Liquidity and Capital Resources*

As of December 31, 2024, we had cash, cash equivalents and short-term investments of \$90.1 million. Our cash used in operations for the year ended December 31, 2024 was \$148.8 million and included a net loss for the year of \$156.8 million. Pursuant to a covenant in the Credit Agreement entered on June 3, 2024, we must maintain \$25.0 million of unrestricted cash, cash equivalents and short-term investments at all times (see “Note 6 - Debt”).

In recent years, Omeros has incurred net losses from continuing operations and negative cash flows from operations. The recurring losses, in combination with our cash and investment balances as of December 31, 2024, and an expected repayment of a portion of the borrowings under our secured credit facility on or prior to November 1, 2025, along with the maturity of the 2026 Notes on February 15, 2026, raises substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of

assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.

As we currently do not have an ongoing source of revenue sufficient to cover our operating costs, we will need to raise additional capital to accomplish our business plan. 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 of up to \$150.0 million. In addition, our Delayed Draw Term Loan of \$25.0 million may be drawn once in full upon notice delivered on or prior to June 3, 2025, conditioned on receipt of FDA approval of narsoplimab in TA-TMA within 30 days of the notice; however, we do not expect that FDA approval of narsoplimab will be obtained within a timeframe that would permit the Delayed Draw Term Loan to be drawn absent an amendment to, or waiver of, this condition. Proceeds of the Delayed Draw Term Loan, if available, may only be used towards any related transaction costs and for commercialization of narsoplimab efforts of TA-TMA.

We may pursue additional debt financings to retire the 2026 Notes that remain outstanding and to fund operations. Should it be necessary or determined to be strategically advantageous, we also could pursue public and private offerings of our equity securities, additional debt transactions or restructurings, future royalty sales, or other strategic transactions, which may include licensing or selling a portion or all of one or more of our existing technologies. However, pursuing debt financings, certain equity offerings or other strategic transactions may result in mandatory prepayments of the Initial Term Loan to the Credit Agreement. (see “Note 6 — Debt” for further details).

If these capital resources, for any reason, are needed but inaccessible, it would have a significant negative impact on our financial condition. For purposes of determining available capital resources, future royalty and/or milestone receipts are excluded. Should it be necessary, we plan to manage our operating expenses and reduce our projected cash requirements by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

The conditions described above, when evaluated in accordance with the relevant accounting literature, raise substantial doubt with respect to our ability to meet our obligations through one year from the issuance of the Company's consolidated financial statements.

#### *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 the OMIDRIA contract royalty asset valuation and the OMIDRIA royalty obligation valuation. 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**

#### *Segment Reporting*

We operate in one business segment focusing on the research, discovery, development and commercialization of small-molecule and protein therapeutics targeting immunologic diseases, including complement-mediated diseases and cancers related to dysfunction of the immune system, as well as addictive and compulsive disorders. The Company defines its operating segment based on internally reported financial information that is regularly used by the Chief Operating Decision Maker (“CODM”) to analyze performance, make decisions and allocate resources. The Company's CODM is our Chief Executive Officer. For the year ended December 31, 2024, the Company has identified one operating and reportable segment. The CODM reviews net loss and expenses reported on the consolidated statement of operations and comprehensive income (loss). The measurement of segment assets is reported on the balance sheet as total consolidated assets. All long-lived assets are held in the U.S. Our segment net income (loss) aligns with our consolidated statement of operations and comprehensive income (loss).

#### *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 use 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, in December 2022, we earned a \$200.0 million milestone payment (the “Milestone Payment”) upon the establishment of 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”). We received \$200.0 million in February 2023. Upon achieving the Milestone Event, the royalty rate applicable to U.S. net sales of OMIDRIA was reduced from 50% to 30%. The 30% royalty rate 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, in December 2022, 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 a portion of our future OMIDRIA royalty receipts for a purchase price of \$125.0 million and recorded an OMIDRIA Royalty Obligation for the same amount. On February 1, 2024, DRI purchased our remaining U.S. OMIDRIA royalty receipts through December 31, 2031 for \$115.5 million in cash, which increased the OMIDRIA royalty obligation by the same amount. The OMIDRIA royalty obligation is valued based on our estimates of future OMIDRIA royalties and is amortized through December 31, 2031 using the implied effective interest rate of 10.27%. Interest expense is recorded as a component within continuing operations.

To the extent our estimates of future royalties differ materially from the previous estimates, we will adjust for future OMIDRIA royalties to the present value of the revised estimated cash flows, discounted at the implied effective interest rate of 10.27% utilizing the cumulative catch-up method. The offset to the adjustment would be recognized as non-cash interest expense, 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 instruments 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, except for money market funds which are classified as available-for-sale. Investments classified as available-for-sale are measured at fair value. 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 within 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 on our office lease.

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 primarily consist of royalties receivable from Rayner. Considering the nature of our receivables, we concluded an allowance for doubtful accounts was not necessary as of December 31, 2024 and 2023, 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 between three to 10 years. Expenditures for repairs and maintenance are expensed as incurred.

### *Right-of-Use Assets and Related Lease Liabilities*

We record operating leases as right-of-use assets and recognize the related lease liabilities equal to the fair value of the lease payments using our incremental borrowing rate when the implicit rate in the lease agreement is not readily available. We recognize variable lease payments when incurred. Costs associated with operating lease assets are recognized on a straight-line basis within operating expenses over the term of the lease.

We record finance lease obligations as a component of property and equipment and amortize these assets within operating expenses on a straight-line basis to their residual values over the shorter of the term of the underlying lease or the estimated useful life of the equipment. The interest component of finance lease obligations is included in interest expense and recognized using the effective interest method over the lease term.

We account for leases with initial terms of 12 months or less as an operating expense.

### *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, 2024, 2023 and 2022.

### *Payment on Maturity of the 2023 Notes*

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. On November 15, 2023, we extinguished our 6.25% convertible senior notes (the “2023 Notes”) at par upon maturity.

### *Repurchase of 2026 Notes*

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.

In June 2024, we performed an assessment of the Credit Agreement which was entered into with Highbridge and Athyrium and determined that it met the criteria to be accounted for as a troubled debt restructuring. As a result, the \$29.3 million difference between the \$118.1 million aggregate principal amount of the 2026 Notes exchanged and the \$88.8 million aggregate repurchase price (consisting of the \$67.1 million Initial Term Loan and \$21.7 million cash on hand) was recorded as a premium (i.e. an increase) to the term debt recorded on the Company's consolidated balance sheet instead of being recognized as a gain on early extinguishment of debt. The premium will be amortized as both a reduction of term debt in the consolidated balance sheet and interest expense in the consolidated statement of operations and comprehensive income (loss) over the duration of the term loan.



### *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 expenses; professional and legal services; patent costs; and salaries, benefits, and stock-compensation costs for 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, 2024, 2023 and 2022.

### *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 by the relevant taxing authority. 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 based on estimated fair values. The fair value of our stock is calculated using the Black-Scholes option-pricing model, which requires assumptions around volatility, forfeiture rates, risk-free interest 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 have repurchased 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 in the consolidated financial statements. The terms of the Credit Agreement dated June 3, 2024 prohibit us from repurchasing our common stock, unless agreed to by the Lenders. Consequently, the Board of Directors terminated the active share repurchase program effective upon the execution of the Credit Agreement.

### *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 were no differences between comprehensive income (loss) and net income (loss) for the years ended December 31, 2024, 2023 and 2022.

### *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 (“FASB”) 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 beginning after December 15, 2024 and applied prospectively. The Company is evaluating the impact of this pronouncement on its consolidated financial statements.

In November 2024, the FASB issued 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): *Disaggregation of Income Statement Expense*, requiring public entities to disclose additional information about specific expense categories in the notes to the financial statements on an interim and annual basis. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact on its financial statement disclosures.

### 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 because the effect would be antidilutive. Potentially dilutive securities excluded from Diluted EPS are as follows:

	Year Ended December 31,		
	2024	2023	2022
2026 Notes convertible to common stock <sup>(1)(2)</sup>	7,980,438	11,132,366	12,172,008
2023 Notes convertible to common stock <sup>(3)</sup>	—	4,318,944	4,941,739
Outstanding options to purchase common stock	252,397	38,462	9,488
Outstanding restricted stock units <sup>(4)</sup>	—	—	98,750
Total dilutive shares excluded from net income (loss) per share	8,232,835	15,489,772	17,221,985

(1) The 2026 Notes are subject to a capped call arrangement that potentially reduces the dilutive effect as described in “Note 6 - Debt”. Any potential impact of the capped call arrangement is excluded from this table.

(2) In December 2023 and on June 3, 2024, we repurchased \$9.1 million and \$118.1 million of our 2026 Notes, respectively, reducing an effect of dilution related to those notes. For further details refer to “Note 6 - Debt.”

(3) The 2023 Notes were fully extinguished upon maturity on November 15, 2023.

(4) The outstanding restricted stock units were vested and converted to shares of common stock on December 1, 2023.

### Note 4—Investments and Fair-Value Measurements

All of our investments are short-term and held in our name. Money market funds are classified as available-for-sale and treasury bills are classified as held-to-maturity on the accompanying consolidated balance sheets. Interest income is included as a component of interest and other income on our consolidated statement of operations and comprehensive income (loss). Interest and other income for the years ended December 31, 2024, December 31, 2023 and December 31, 2022 consists primarily of interest earned from investments of \$8.4 million, \$14.7 million and \$2.2 million, respectively.

The following tables summarize our investments:

	December 31, 2024		
	Gross Unrealized		Estimated Fair Value
	Amortized Cost	Gains/(Losses) (In thousands)	
Money-market funds classified as short-term investments	\$ 86,732	\$ —	\$ 86,732
Certificate of deposit classified as non-current restricted investments	1,054	—	1,054
Total investments	<u>\$ 87,786</u>	<u>\$ —</u>	<u>\$ 87,786</u>

	December 31, 2023		
	Gross Unrealized		Estimated Fair Value
	Amortized Cost	Gains/(Losses) (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	<u>\$ 165,797</u>	<u>\$ 19</u>	<u>\$ 165,816</u>

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, 2024			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as short-term investments	\$ 86,732	\$ —	\$ —	\$ 86,732
Certificate of deposit classified as non-current restricted investments	1,054	—	—	1,054
Total investments	<u>\$ 87,786</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 87,786</u>

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
U.S. government treasury bills 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
Certificate of deposit classified as non-current restricted investments	1,054	—	—	1,054
Total investments	<u>\$ 63,697</u>	<u>\$ 102,119</u>	<u>\$ —</u>	<u>\$ 165,816</u>

Unrealized gains and losses on our short-term investments were not material for either period presented. Cash held in demand deposit accounts of \$3.4 million and \$7.1 million is excluded from our fair-value hierarchy disclosure as of December 31, 2024 and 2023, 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 - Debt” and “Note 8 – OMIDRIA Royalty Obligation” for the carrying amount and estimated fair value of our outstanding term loan, 2026 Notes and the OMIDRIA royalty obligation.

#### Note 5—Certain Balance Sheet Accounts

##### Receivables

Receivables consists of the following:

	December 31, 2024	December 31, 2023
	(In thousands)	
OMIDRIA royalty receivables	\$ 6,940	\$ 6,724
Other receivables	799	1,372
Total receivables	<u>\$ 7,739</u>	<u>\$ 8,096</u>

##### Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31, 2024	December 31, 2023
	(In thousands)	
Equipment under finance leases	\$ 8,323	\$ 6,929
Laboratory equipment	3,690	3,525
Computer equipment	1,113	1,113
Office equipment and furniture	624	624
Total cost	13,750	12,191
Less accumulated depreciation and amortization	(11,072)	(10,241)
Total property and equipment, net	<u>\$ 2,678</u>	<u>\$ 1,950</u>

For the years ended December 31, 2024, 2023 and 2022, depreciation and amortization expenses were \$1.0 million, \$0.9 million and \$1.0 million, respectively.

### *Accrued Expenses*

Accrued expenses consist of the following:

	December 31, 2024	December 31, 2023
	(In thousands)	
Employee compensation	\$ 8,868	\$ 7,380
Clinical trials	7,100	10,168
Contract research and development	4,334	6,223
Interest payable	2,667	4,242
Consulting and professional fees	2,602	3,539
Other accrued expenses	434	316
Total accrued expenses	<u>\$ 26,005</u>	<u>\$ 31,868</u>

### **Note 6—Debt**

#### *Secured Term Debt*

On June 3, 2024, we entered into a Credit Agreement, which provides for a term loan credit facility of up to \$92.1 million, in aggregate, consisting of an Initial Term Loan of \$67.1 million and a Delayed Draw Term Loan of \$25.0 million. The Delayed Draw Term Loan may be drawn once in full upon notice delivered on or prior to June 3, 2025, conditioned on receipt of FDA approval of narsoplimab in TA-TMA within 30 days of the notice; however, we do not expect that FDA approval of narsoplimab will be obtained within a timeframe that would permit the Delayed Draw Term Loan to be drawn absent an amendment to, or waiver of, this condition. The Delayed Draw Term Loan would be issued with an original issue discount of 3.0% and the proceeds may be used only for commercialization of narsoplimab in TA-TMA and transaction costs associated with the Delayed Draw Term Loan. Until the earlier of November 1, 2025 and the date we elect to utilize the Delayed Draw Term Loan, the Company, at its sole discretion, may exchange up to \$14.9 million aggregate principal amount of outstanding 2026 Notes for cash and/or additional term loan amounts, with the holders of such notes becoming Lenders under the Credit Agreement (any such additional term loans, together with the Initial Term Loan and the Delayed Draw Term Loan, the “Loans”). As of December 31, 2024, no such additional exchanges have occurred. All indebtedness under the Credit Agreement is secured by a first-priority security interest in and lien on substantially all our tangible and intangible property, subject to customary exceptions, and excluding royalty interests in OMIDRIA and certain related rights.

In connection with our entry into the Credit Agreement, we used the Initial Term Loan of \$67.1 million along with \$21.7 million of cash on hand to repurchase \$118.1 million aggregate principal amount of the 2026 Notes held by the Lenders. The total aggregate purchase price of \$88.8 million represented a purchase price equal to approximately 75% of the par value of the 2026 Notes retired in the transaction. The reduction in the aggregate outstanding principal balance of our 2026 Notes and incurrence of a new Initial Term Loan resulted in a \$51.0 million reduction of our outstanding debt. The \$29.3 million difference between the \$118.1 million aggregate principal amount of the 2026 Notes and the \$88.8 million aggregate repurchase price was recorded as a premium (i.e., an increase) to the long-term debt on the Company’s consolidated balance sheet instead of being recognized as a gain on early extinguishment of debt. The premium is being amortized as both a non-cash reduction of long-term debt in the consolidated balance sheets and interest expense in the consolidated statement of operations and comprehensive income (loss) over the duration of the term loan.

The amount outstanding on the Initial Term Loan is as follows:

	December 31, 2024
	(In thousands)
Principal amount	\$ 67,077
Unamortized debt premium, net of issuance costs and other	23,328
Total term debt, net	90,405

The Loans have a stated maturity date of June 3, 2028 and bear interest at an adjusted secured overnight financing rate (“adjusted SOFR”), subject to a 3.0% floor, plus 8.75% per annum, payable quarterly from the closing date. As of December 31, 2024, the contractual interest rate on the Loans was 13.32%. We have the option to pay all of the interest in cash or to pay 50% in cash and pay-



in-kind (“PIK”), the remaining interest. When this provision is elected, interest for the quarter, including both the cash interest and PIK interest, is calculated based on adjusted SOFR plus a 10.25% PIK margin (instead of the customary 8.75% margin). The PIK interest is then added to the outstanding principal balance and interest is computed using the original adjusted SOFR plus 8.75% margin rate. Due to the premium amortization on the Initial Term Loan, interest expense is currently being recognized at an implied effective interest rate of 1.50%.

The following table sets forth interest expense recognized related to the Initial Term Loan:

	<b>Twelve Months Ended December 31, 2024</b>
	<b>(In thousands)</b>
Contractual interest expense	\$ 5,525
Amortization of premium and debt issuance costs	(4,681)
<b>Total interest expense</b>	<b>\$ 844</b>

We may elect to prepay the Loans, in whole or in part, in cash, plus an applicable prepayment and/or make-whole premium. Under certain circumstances, we are required to prepay all or a portion of the outstanding Loans, plus an applicable prepayment and/or make-whole premium, as described below.

- (1) If, on November 1, 2025, (i) the aggregate outstanding principal amount of the outstanding 2026 Notes that is not held by the Lenders equals or exceeds \$38.5 million and (ii) we have not made or delivered notice that we expect to make certain voluntary or mandatory prepayments under the Credit Agreement of at least \$20.0 million in the aggregate, then we would be required, on or prior to November 15, 2025, to make a \$20.0 million mandatory prepayment, together with a \$1.0 million prepayment premium.
- (2) Upon the occurrence of a change in control, we must prepay the entire outstanding amount of the Loans, plus the applicable make-whole or prepayment premium.
- (3) We must prepay the Loans in an amount equal to: (i) 25.0% of any milestone payments received from DRI or its affiliates on the basis of net sales of OMIDRIA; (ii) 60.0% of the net cash proceeds (excluding transaction expenses and certain milestone payments) received by Omeros from the sale or license of our assets (or in the case of an asset sale or license involving narsoplimab that occurs while any Delayed Draw Term Loan is outstanding, an amount equal to 100% of the net cash proceeds from such transaction); (iii) 100.0% of net cash proceeds of indebtedness incurred by the Company other than as permitted by the Credit Agreement; and (iv) 100% of the net cash proceeds of insurance recoveries on loss of property, except to the extent utilized to repair or replace the relevant assets within a specified time.

Voluntary and mandatory prepayments of the Loans are subject to payment of the following premiums: (i) during the first year of such Loans, a make-whole premium plus 5.0% of the applicable prepayment amount (unless the prepayment is made in contemplation of a change of control, in which case only the make-whole premium would be payable); (ii) during the second year, a prepayment premium equal to 5.0% of the applicable prepayment amount; and (iii) during the third year, a prepayment premium equal to 3.0% of the applicable prepayment amount.

The Credit Agreement contains certain customary default provisions, representations and warranties and affirmative and negative covenants. These include a covenant requiring us to maintain at all times unrestricted cash, cash equivalents and short-term investments of at least \$25.0 million in accounts subject to control agreements and a covenant limiting the use of cash for open market or privately negotiated repurchases of any outstanding 2026 Notes to: (i) an initial amount not exceeding \$25.0 million, which may be increased by up to an additional \$10.0 million subject to the satisfaction of certain conditions; (ii) an unlimited amount, if the amount of the Loans outstanding at the time of repurchase does not exceed \$38.5 million; and (iii) an additional amount not to exceed 50% of the net cash proceeds from an equity offering, provided that the Company offers to prepay an equal amount of the Loans with the net cash proceeds of such offering. As of December 31, 2024, the Company was in compliance with the covenants under the Credit Agreement. After review of the customary default provisions, affirmative and negative covenants, and voluntary and mandatory prepayment options, we determined that the net derivative asset was not significant as of December 31, 2024. A default under the Credit Agreement that results in the outstanding debt thereunder being declared due and payable prior to the stated maturity would constitute a cross-default under the indenture governing the 2026 Notes. In such an event, the principal and all accrued and unpaid interest on the 2026 Notes may be declared immediately due and payable either by the trustee under the indenture, or by the holders of at least 25% of the aggregate principal amount of the 2026 Notes outstanding.

The fair value of the Loans is classified as a Level 3 liability. As of December 31, 2024, the approximate fair value of our Loan obligations was \$69.5 million. We determined the fair market value by discounting the future cash flows based on adjusted SOFR at each measurement date.

### **2023 Unsecured Convertible Senior Notes**

We extinguished the \$95.0 million outstanding on our 2023 Notes at par upon maturity on November 15, 2023. The following table sets forth interest expense recognized related to the 2023 Notes.

	Year Ended December 31,		
	2024	2023	2022
	(In thousands)		
Contractual interest expense	\$ —	\$ 5,195	\$ 5,938
Amortization of debt issuance costs	—	619	663
Total interest expense	\$ —	\$ 5,814	\$ 6,601

### **2026 Unsecured Convertible Senior Notes**

We have outstanding unsecured convertible senior notes which 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.

In 2024, we repurchased \$118.1 million of principal amount outstanding on our 2026 Notes for a total aggregate repurchase price of \$88.8 million (approximately 75% of par value), using proceeds from the Initial Term Loan of \$67.1 million and paying \$21.7 million of cash on hand.

Amounts outstanding on our 2026 Notes are as follows:

	December 31, 2024	December 31, 2023
	(In thousands)	
Principal amount	\$ 97,862	\$ 215,924
Unamortized debt issuance costs	(684)	(2,769)
Total convertible senior notes, net	\$ 97,178	\$ 213,155
Fair value of outstanding convertible senior notes <sup>(1)</sup>	\$ 93,752	\$ 131,444

(1) The fair value is classified as Level 2 liability due to the limited trading activity for the unsecured convertible senior notes. The fair value of the 2026 Notes is determined based on quoted prices in an over-the counter market using the most recent trading information available at the end of the reporting period. The value of the conversion feature of the 2026 Notes is not deemed to be significant as the current market price of our common stock is below the initial conversion price of \$18.49 per share of common stock.

The unamortized debt issuance costs of \$0.7 million as of December 31, 2024 will be amortized to interest expense at an effective interest rate of 5.89% over the remaining term.

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

	Year Ended December 31,		
	2024	2023	2022
	(In thousands)		
Contractual interest expense	\$ 7,772	\$ 11,774	\$ 11,814
Amortization of debt issuance costs	859	1,355	1,167
Total interest expense	\$ 8,631	\$ 13,129	\$ 12,981

The 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 5.3 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, 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. 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 \$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, 2024, approximately 12.2 million shares remained outstanding under the 2026 Capped Call. We also retain all potential future value of the capped call purchased in connection with the issuance of the 2026 Notes covering all shares underlying the original 2026 Notes.

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.

## Minimum Commitments

As of December 31, 2024, the most probable principal payments on our 2026 Notes and Term Loan are as follows:

	2026 Notes	Term Loan (In thousands)	Total
2025	\$ —	\$ 20,000	\$ 20,000
2026	97,862	—	97,862
2027	—	—	—
2028	—	47,077	47,077
2029 and thereafter	—	—	—
Total principal payments	97,862	67,077	164,939
Unamortized premiums, discounts and issuance costs and other <sup>(1)</sup>	(684)	23,328	22,644
Carrying value of debt	\$ 97,178	\$ 90,405	\$ 187,583

(1) Under the Term Loan, we expect to pay a \$1.0 million prepayment penalty in November 2025 which is included in the current portion of term debt in the consolidated balance sheet. As this is not a principal payment it is included as a component of other costs herein.

## Note 7—Discontinued Operations - Sale of OMIDRIA

On December 23, 2021, we sold the rights to OMIDRIA and related assets to Rayner, which is reported as discontinued operations in our consolidated statements of operations and comprehensive income (loss) and excluded from continuing operations for all periods presented.

In December 2022, we earned a \$200.0 million Milestone Payment upon the occurrence of an event specified in the Asset Purchase Agreement with Rayner. The Milestone Payment was 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) are as follows:

	Year Ended December 31,		
	2024	2023	2022
	(In thousands)		
Interest on OMIDRIA contract royalty asset	\$ 16,922	\$ 15,315	\$ 18,634
Remeasurement adjustments	7,969	41,167	14,457
Other income	1,211	1,087	307
Milestone income	—	—	200,000
Income before income tax	26,102	57,569	233,398
Income tax expense <sup>(1)</sup>	(288)	(462)	(3,952)
Net income from discontinued operations, net of tax	\$ 25,814	\$ 57,107	\$ 229,446

(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, 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
Royalties earned	(39,651)
Interest on OMIDRIA contract royalty asset	16,922
Remeasurement adjustments	7,969
Balance at December 31, 2024	\$ 153,349

Cash flow from discontinued operations is as follows:

	Year Ended December 31,		
	2024	2023	2022
	(In thousands)		
Net cash provided by discontinued operations from operating activities	\$ 40,484	\$ 243,405	\$ 78,082

Net cash provided by discontinued operations primarily represents royalties received and the \$200.0 million milestone payment that we collected from Rayner in February 2023. All royalties earned on OMIDRIA sales within the U.S. through December 31, 2031 are remitted by Rayner to an escrow account established by Omeros, from which payments are made to DRI.

#### 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 was entitled to receive royalties on OMIDRIA net sales between September 1, 2022 and December 31, 2030 up to certain annual cap limits.

In February 2024, Omeros and DRI expanded their royalty purchase agreement under the Amendment, resulting in the elimination of previously existing annual caps on royalty payments and Omeros receiving an additional \$115.5 million in cash consideration which we accounted for as a modification of our existing debt from DRI. All royalties earned on OMIDRIA sales within the U.S. through December 31, 2031 are remitted by Rayner to an escrow account established by Omeros, from which payments are made to DRI.

We retain the right to receive all royalties payable by Rayner on any U.S. net sales of OMIDRIA after December 31, 2031 and all royalties on global net sales of OMIDRIA from and after December 31, 2031. To date, international royalties have not been significant. DRI has no recourse to our assets other than in its interest in OMIDRIA royalties.

We are also entitled 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 prior to January 1, 2026. In addition, we are entitled to receive 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 prior to January 1, 2028.

The changes in the OMIDRIA royalty obligation during the year ended December 31, 2024 are as follows (in thousands):

Balance at December 31, 2022	\$ 126,278
Principal payments	(1,152)
Balance at December 31, 2023	125,126
Additional proceeds	115,525
Principal payments	(18,780)
Non-cash interest	(5,614)
Balance at December 31, 2024	<u>\$ 216,257</u>

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. The fair value of the OMIDRIA royalty obligation is determined by calculating the net present value of our estimated future OMIDRIA cash flows using the interest rate at inception of our royalty purchase agreement with DRI, adjusted for the change in the prime rate through the remeasurement date. As of December 31, 2024, the approximate fair value of our obligation was \$209.7 million.

For the years ended December 31, 2024, 2023 and 2022, we incurred interest expense of \$15.0 million, \$11.8 million and \$2.9 million, respectively, on the OMIDRIA royalty obligation.



As of December 31, 2024, the expected scheduled principal and interest payments (based on an implied effective interest rate of 10.27%) are as follows:

	<b>Principal</b>	<b>Interest</b>	<b>Total</b>
	<b>(In thousands)</b>		
2025	\$ 20,645	\$ 20,056	\$ 40,701
2026	23,304	17,947	41,251
2027	26,528	15,548	42,076
2028	30,096	12,822	42,918
2029	34,043	9,733	43,776
Thereafter	81,641	8,553	90,194
Total scheduled payments	<u>\$ 216,257</u>	<u>\$ 84,659</u>	<u>\$ 300,916</u>

## 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 October 2029.

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

	<b>December 31, 2024</b>	<b>December 31, 2023</b>
	<b>(In thousands)</b>	
<b>Assets</b>		
Operating lease assets	\$ 14,961	\$ 18,631
Finance lease assets, net	2,025	1,220
Total lease assets	<u>\$ 16,986</u>	<u>\$ 19,851</u>
<b>Liabilities</b>		
<b>Current:</b>		
Operating leases	\$ 5,239	\$ 4,590
Finance leases	732	570
<b>Non-current:</b>		
Operating leases	12,224	17,424
Finance leases	1,242	719
Total lease liabilities	<u>\$ 19,437</u>	<u>\$ 23,303</u>
<b>Weighted-average remaining lease term</b>		
Operating leases (years)	2.9	3.8
Finance leases (years)	3.5	2.3
<b>Weighted-average discount rate</b>		
Operating leases	12.62%	12.81%
Finance leases	5.87%	8.57%

The components of total lease costs are as follows:

	Year Ended December 31,	
	2024	2023
	(In thousands)	
Lease cost		
Operating lease cost	\$ 6,403	\$ 6,464
Finance lease cost:		
Amortization	708	677
Interest	171	174
Variable lease cost	3,471	3,160
Sublease income	(1,589)	(1,500)
Net lease cost	<u>\$ 9,164</u>	<u>\$ 8,975</u>

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

	Year Ended December 31,	
	2024	2023
	(In thousands)	
Cash paid for amounts included in the measurement of lease liabilities		
Cash payments for operating leases	\$ 7,003	\$ 7,144
Cash payments for financing leases	944	655

The future maturities of our lease liabilities as of December 31, 2024 are as follows:

	Operating Leases	Finance Leases	Total
	(In thousands)		
2025	\$ 6,912	\$ 826	\$ 7,738
2026	7,144	569	7,713
2027	6,123	299	6,422
2028	—	272	272
2029	—	201	201
Total undiscounted lease payments	20,179	2,167	22,346
Less interest	(2,716)	(193)	(2,909)
Total lease liabilities	<u>\$ 17,463</u>	<u>\$ 1,974</u>	<u>\$ 19,437</u>

## Note 10—Commitments and Contingencies

### Contracts

We have various agreements with third parties that collectively require payment of termination fees totaling \$4.7 million as of December 31, 2024 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 year ended December 31, 2024, we did not pay any development milestones. For the years ended December 31, 2023 and 2022, we paid \$5.0 million and \$0.3 million, respectively in development milestones.

## Note 11—Shareholders' Equity (Deficit)

### Common Stock

As of December 31, 2024, we had reserved shares of common stock under our equity plans as follows:

Stock options outstanding	16,690,882
Awards available to issue under the 2017 Plan	6,881,912
Total shares reserved	23,572,794

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 a share repurchase program under which we were permitted to 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 price of \$2.54 per share for an aggregate purchase price of \$4.7 million. During the first quarter of 2024, we repurchased and retired 3.2 million shares of common stock at an average of \$3.71 per share for an aggregate purchase price of \$11.9 million. The terms of the Credit Agreement prohibit us from repurchasing our common stock unless expressly agreed to by the Lenders. Consequently, the Board of Directors terminated the share repurchase program effective upon execution the Credit Agreement in June 2024.

## 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,		
	2024	2023	2022
	(In thousands)		
Continuing operations:			
Research and development	\$ 4,133	\$ 4,754	\$ 6,123
Selling, general and administrative	6,360	7,140	8,042
Total stock-based compensation in continuing operations	10,493	11,894	14,165
Discontinued operations	—	(244)	(93)
Total stock-based compensation	\$ 10,493	\$ 11,650	\$ 14,072

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,		
	2024	2023	2022
Estimated weighted-average fair value	\$ 2.68	\$ 2.44	\$ 2.94
Weighted-average assumptions:			
Expected volatility	95%	93%	90%
Expected life, in years	7.2	7.2	6.0
Risk-free interest rate	4.36%	3.97%	2.83%
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, 2023	15,255,154	\$ 9.50		
Granted	3,331,300	3.24		
Exercised	(111,109)	4.84		
Forfeited	(1,784,463)	10.54		
Balance at December 31, 2024	16,690,882	\$ 8.17	6.3	\$ 55,738
Vested and expected to vest at December 31, 2024	16,126,986	\$ 8.33	6.2	\$ 52,103
Exercisable at December 31, 2024	11,331,705	\$ 10.35	5.0	\$ 20,994

Of the 16.7 million common stock options outstanding as of December 31, 2024, 8.2 million have an exercise price above the \$9.88 closing price of our stock on the Nasdaq exchange on December 31, 2024. The total intrinsic value of stock options exercised during the years ended December 31, 2024, 2023 and 2022 was \$0.5 million, \$0.1 million and \$0.2 million, respectively.

At December 31, 2024 and December 31, 2023, there were 5.4 million and 4.7 million unvested stock options outstanding, respectively, that vest over a weighted-average period of 2.4 years and 2.1 years, respectively. The remaining estimated compensation expense to be recognized in connection with these unvested stock options is \$12.5 million and \$14.5 million for the years ended December 31, 2024 and December 31, 2023, respectively.

## Note 13—Income Taxes

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

		December 31,	
	2024	2023	2022
	(In thousands)		
Continuing operations:			
Current income tax expense:			
Federal	\$ —	\$ —	\$ —
State	2,305	—	—
Total current income tax expense	2,305	—	—
Deferred income tax benefit:			
Federal	—	—	—
State	—	—	—
Total deferred income tax benefit	—	—	—
Income tax expense in continuing operations	\$ 2,305	\$ —	\$ —
Income tax expense as a component of discontinued operations	\$ 288	\$ 462	\$ 3,952

For the year ended December 31, 2024, for federal and state income tax purposes, we have net income from continuing operations and from discontinued operations. For the years ended December 31, 2023 and 2022, we had net losses from continuing operations and net income from discontinued operations. At December 31, 2024, 2023 and 2022, we had federal net operating loss (“NOL”) carryforwards of approximately \$331.7 million, \$398.6 million and \$361.4 million, respectively. At December 31, 2024, 2023 and 2022, we had state NOL carryforwards of approximately \$233.2 million, \$245.8 million and \$226.3 million, respectively. In 2024 and 2022, we had net income for federal income tax purposes. Therefore, we utilized existing NOLs of \$62.5 million and \$268.6 million, respectively, to fully offset our federal tax liability for both periods. In 2023, we had a net loss for federal income tax purposes and no federal tax liability. We recorded state income tax expense of \$0.3 million, \$0.5 million and \$4.0 million in discontinued operations in 2024, 2023 and 2022, respectively, as we did not have adequate NOLs and tax credits to fully offset our state tax liability.

Deferred income tax assets and liabilities reflect the tax effect of NOL 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:

	<b>December 31,</b>	
	<b>2024</b>	<b>2023</b>
	<b>(In thousands)</b>	
Deferred tax assets:		
Net operating loss carryforwards	\$ 80,414	\$ 95,183
Research and development tax credits	104,772	92,837
Capitalized research and development	52,388	39,318
OMIDRIA royalty obligation	50,446	28,903
Stock-based compensation	9,573	10,132
Lease liability	4,074	5,085
Other	21,907	10,283
Total deferred tax assets	323,574	281,741
Deferred tax liabilities:		
OMIDRIA contract royalty asset	(35,772)	(38,832)
Right of use assets	(3,490)	(4,304)
Property and equipment	(349)	(122)
Total deferred tax liabilities	(39,611)	(43,258)
Net deferred tax assets before valuation allowance	283,963	238,483
Less valuation allowance	(283,963)	(238,483)
Net deferred tax liabilities	\$ —	\$ —

As of December 31, 2024, we had federal NOL carryforwards of approximately \$331.7 million and state NOL carryforwards of approximately \$233.2 million. Pre-2018 federal NOLs of \$45.2 million expire between 2035 and 2037. Post-2018 federal NOLs of \$286.5 million do not expire. Research and development tax credit carryforwards of \$104.9 million expire between 2025 and 2044.

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:

	<b>Year ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
U.S. federal statutory rate on net loss	(21.0)%	(21.0)%	(21.0)%
State tax, net of federal tax benefit	(2.3)%	(2.1)%	(1.7)%
Change in valuation allowance	28.2%	27.7%	28.3%
Tax credits	(6.6)%	(8.0)%	(6.8)%
Nondeductible items	0.1%	0.0%	0.0%
Stock compensation	1.7%	1.5%	1.4%
Other	1.2%	1.9%	(0.2)%
Effective tax rate	1.3%	0.0%	(0.0)%

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



As of December 31, 2024, 2023 and 2022, the total amount of gross unrecognized tax benefits was \$4.5 million, \$2.0 million and \$0.2 million, respectively. Interest and penalties of \$0.5 million and \$0.3 million, respectively, were included within our unrecognized tax benefits as of December 31, 2024 and December 31, 2023. As of December 31, 2024, \$4.2 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 uncertain tax positions for the next 12 months. The Company's 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
Increase in balance related to tax positions taken during current year		2,509
Decrease in balance as a result of a lapse of the applicable statute of limitations		(12)
Balance at December 31, 2024	\$	<u>4,463</u>

#### Note 14—401(k) Retirement Plan

Our 401(k) retirement plan provides for an annual company discretionary match on employee contributions. For all three years ended December 31, 2024, 2023 and 2022, Omeros' 401(k) match expense was \$0.6 million. We match up to 4.0% of each participant's eligible earnings, with a maximum annual company match of \$4,000 per employee. All employees are eligible to participate in the 401(k) match.

**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, 2024. 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, 2024, 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, 2024. 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, 2024.

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 2024 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, 2024, 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 2025 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 2025 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 2025 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, 2024:

	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
<i>Equity compensation plans approved by security holders:</i>			
2017 Omnibus Incentive Compensation Plan <sup>(1)</sup>	13,966,710	\$ 7.57	6,881,912
2008 Equity Incentive Plan <sup>(2)</sup>	2,724,172	\$ 11.25	—
Total	16,690,882	\$ 8.17	6,881,912

- (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 2025 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 2025 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

Exhibit No.	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit No.	Filing Date	
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. Demopoulos, 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	Fifteenth Amendment to Lease dated November 1, 2022 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.3	08/07/2024
10.24	Sixteenth Amendment to Lease dated July 8, 2024 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.1	11/13/2024
10.25	Seventeenth Amendment to Lease dated December 18, 2024 between Omeros Corporation and BMR-201 Elliott Avenue LLC				X
10.26†	License Agreement between Omeros Corporation and Daiichi Sankyo Co., Ltd. (successor-in-interest to Asubio Pharma Co., Ltd.) dated March 3, 2010	10-K	001-34475	10.23	04/01/2024
10.27†	Amendment No. 1 to License Agreement with an effective date of January 5, 2011 between Omeros Corporation and Daiichi Sankyo Co., Ltd.	10-K	001-34475	10.24	04/01/2024



10.28†	Amendment No. 2 to License Agreement with an effective date of January 25, 2013 between Omeros Corporation and Daiichi Sankyo Co., Ltd.	10-K	001-34475	10.25	04/01/2024	
10.29	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	
10.30†	Combined Development and Commercial Supply Agreement, effective as of May 16, 2018, between Omeros Corporation and Vetter Pharma international GmbH					X
10.31†	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	
10.32†	Technology License Agreement, effective August 28, 2020 between Omeros Corporation and Xencor, Inc.	10-K	001-34475	10.1	03/13/2023	
10.33†	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	
10.34†	Amended and Restated Royalty Purchase Agreement between Omeros Corporation and DRI Healthcare Acquisitions LP dated February 1, 2024	10-K	001-34475	10.30	04/01/2024	
10.35†	Credit and Guaranty Agreement, dated as of June 3, 2024, among Omeros Corporation, certain subsidiaries of Omeros Corporation, as guarantors, various Lenders and Wilmington Savings Fund Society, FSB, as Administrative Agent and Collateral Agent	8-K	001-34475	10.1	06/03/2024	
10.36	Pledge and Security Agreement, dated as of June 3, 2024, between Omeros Corporation, nura inc. and Wilmington Savings Fund Society, FSB, as Collateral Agent	8-K	001-34475	10.2	06/03/2024	
19.1	Omeros Corporation Insider Trading Policy					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	10-K	001-34475	97.1	04/01/2024	
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

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\* 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: March 31, 2025

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ GREGORY A. DEMOPULOS, M.D.</u> Gregory A. Demopulos, M.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 31, 2025
<u>/s/ DAVID J. BORGES</u> David J. Borges	Vice President, Finance, Chief Accounting Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2025
<u>/s/ THOMAS F. BUMOL, PH.D.</u> Thomas F. Bumol, Ph.D.	Director	March 31, 2025
<u>/s/ THOMAS J. CABLE</u> Thomas J. Cable	Director	March 31, 2025
<u>/s/ PETER A. DEMOPULOS, M.D.</u> Peter A. Demopulos, M.D.	Director	March 31, 2025
<u>/s/ ARNOLD C. HANISH</u> Arnold C. Hanish	Director	March 31, 2025
<u>/s/ LEROY E. HOOD, M.D., PH.D.</u> Leroy E. Hood, M.D., Ph.D.	Director	March 31, 2025
<u>/s/ DIANA PERKINSON, M.D.</u> Diana Perkinson, M.D.	Director	March 31, 2025
<u>/s/ RAJIV SHAH, M.D.</u> Rajiv Shah, M.D.	Director	March 31, 2025

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# CONTACTS + INFORMATION

## Corporate Headquarters

### The Omeros Building

201 Elliott Avenue West

Seattle, WA 98119

206.676.5000

[www.omeross.com](http://www.omeross.com)

## Investor Relations

Investors can contact Omeros Investor Relations by email at [ir@omeross.com](mailto:ir@omeross.com), by calling 206.676.5000 or by writing to Investor Relations at Omeros' corporate headquarters.

## Stock Listing

Omeros' stock trades on The Nasdaq Global Market under the symbol OMER.

For more information, please visit

[www.omeross.com](http://www.omeross.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. Demopoulos, M.D.

Chairman, President  
and Chief Executive Officer  
Omeros Corporation

### Peter A. Demopoulos, 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

### Diana T. Perkinson, M.D.

Physician  
MD<sup>2</sup> International LLC

### Rajiv Shah, M.D.

President  
The Rockefeller Foundation  
Former Administrator of the  
U.S. Agency for International Development

## 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.: 201.6806578

TDD for Hearing Impaired: 800.490.1493 (U.S.)

Outside the U.S.: 781.575.4592

[www.computershare.com/investor](http://www.computershare.com/investor)

## Independent Registered Public Accounting Firm

### Ernst & Young LLP

## 2025 Annual Meeting

The 2025 Annual Meeting of Shareholders of Omeros Corporation will be held via webcast on the Internet on Friday, June 27, 2025, beginning at 10:00 A.M. (Pacific time), at [www.virtualshareholdermeeting.com/OMER2025](http://www.virtualshareholdermeeting.com/OMER2025).

Copies of Omeros' Annual Report on Form 10-K for the fiscal year ended December 31, 2024, including financial statements, as well as other Omeros public documents, are available on the Omeros investor relations website at [investor.omeross.com](http://investor.omeross.com) or by written or telephonic request to Investor Relations at Omeros' corporate headquarters.

## Executive Officers

### Gregory A. Demopoulos, M.D.

Chairman, President and  
Chief Executive Officer

### David J. Borges

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

### David W. Ghesquiere

Vice President,  
Chief Business Development 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," "target," "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 risk, 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**