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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 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

OMEROS CORPORATION

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

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

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

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

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

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

INDEX

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.

OMIDRIA Sale and Royalty Monetization Transactions

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

On December 23, 2021, we sold OMIDRIA 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.

PPARγ Program - OMS405

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

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

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

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

Preclinical Programs and Platforms

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.

- *PPARγ 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 PPARγ and addictive disorders. Our PPARγ-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, 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 additionallegislation, 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.Ds and 41 with Ph.Ds., 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)
Executive Officers:		
Gregory A. Demopulos, 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
Significant Employees:		
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. Demopulos, M.D. founded our company and has served as our president, chief executive officer and chairman of the board of directors since June 1994. He also served as our chief financial officer and treasurer from January 2009 to October 2013 in an interim capacity and as our chief medical officer from June 1994 to March 2010. Prior to founding Omeros, Dr. Demopulos completed his residency in orthopedic surgery at Stanford University and his fellowship training in hand and microvascular surgery at Duke University. Dr. Demopulos currently serves on the board of trustees of the Smead Funds Trust, an open-end mutual fund company registered under the Investment Company Act of 1940. Dr. Demopulos received his M.D. from the Stanford University School of Medicine and his B.S. from Stanford University. Dr. Demopulos is the brother of Peter A. Demopulos, M.D., a member of our board of directors.

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. We make available, free of charge through our investor relations website at investor.omeros.com, our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, including exhibits to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our websites and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with them at www.sec.gov.

ITEM 1A. RISK FACTORS

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

Risks Related to Our 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. Demopulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, without having a readily available and appropriate replacement could delay the execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

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

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

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

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

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

We may be exposed to the risk of product liability claims that is inherent in the biopharmaceutical industry. A product liability claim may damage our reputation by raising questions about our product's safety and efficacy and could limit our ability to sell one or more products by preventing or interfering with commercialization of our 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 in activation of the targeted pathway of complement.

Lectin Pathway / MASP 2

MASP-2 is a novel pro-inflammatory protein target that is the effector enzyme of the lectin pathway and is required for the function of this pathway. 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 the 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	$ 119,523	$ 114,870	$ 112,721

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	$ 49,735	$ 49,660	$ 50,668

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 Athyrium.

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 (1)	(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

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

Description of the Matter	As more fully described in Note 2 of the financial statements, the Company recorded a contract royalty asset in connection with its sale of OMIDRIA to Rayner Surgical, Inc. on December 23, 2021. To measure that contract royalty asset, the Company used the expected value approach, which is the discounted sum of the probability-weighted royalty payments using a range of potential outcomes, to the extent that it is probable that a significant reversal in the amount of cumulative income recognized will not occur. Auditing management's forecasts 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.
How We Addressed the Matter in Our Audit	To test the measurement of the OMIDRIA contract royalty asset, we performed audit procedures that included, among others, evaluating (1) the estimated future royalties in various scenarios, and (2) management's probability weighting of those scenarios. 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.

/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)

	December 31, 2024	December 31, 2023
Assets		
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
Total assets	$ 277,079	$ 378,269
Liabilities and shareholders' equity (deficit)		
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)
Total liabilities and shareholders' equity (deficit)	$ 277,079	$ 378,269

See accompanying Notes to Consolidated Financial Statements

OMEROS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(In thousands, except share and per share data)

	Year Ended December 31,		
	2024	**2023**	**2022**
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	169,258	164,530	163,389
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)	$ (156,815)	$ (117,813)	$ 47,417
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)	$ (2.70)	$ (1.88)	$ 0.76
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)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity/(Deficit)
	Shares	Amount			
Balance at December 31, 2021	62,628,855	$ 626	$ 706,288	$ (683,134)	$ 23,780
Issuance of common stock upon exercise of stock options	101,160	1	414	—	415
Issuance of common stock upon vesting of restricted stock units	98,750	1	(1)	—	—
Stock-based compensation	—	—	14,072	—	14,072
Net income	—	—	—	47,417	47,417
Balance at December 31, 2022	62,828,765	628	720,773	(635,717)	85,684
Issuance of common stock upon exercise of stock options	36,726	—	150	—	150
Issuance of common stock upon vesting of restricted stock units	67,250	1	(1)	—	—
Repurchases of common stock	(1,804,144)	(18)	(4,636)	—	(4,654)
Stock-based compensation	—	—	11,650	—	11,650
Net loss	—	—	—	(117,813)	(117,813)
Balance at December 31, 2023	61,128,597	611	727,936	(753,530)	(24,983)
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)
Balance at December 31, 2024	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**
Operating activities:			
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)
Investing activities:			
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)
Financing activities:			
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
Supplemental cash flow information			
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 divesture, 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 (1)(2)	7,980,438	11,132,366	12,172,008
2023 Notes convertible to common stock (3)	—	4,318,944	4,941,739
Outstanding options to purchase common stock	252,397	38,462	9,488
Outstanding restricted stock units (4)	—	—	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		
	Amortized Cost	Gross Unrealized Gains/(Losses)	Estimated Fair Value
		(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	$ 87,786	$ —	$ 87,786

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

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	$ 87,786	$ —	$ —	$ 87,786

	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	$ 63,697	$ 102,119	$ —	$ 165,816

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	$ 7,739	$ 8,096

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	$ 2,678	$ 1,950

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	$ 26,005	$ 31,868

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:

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

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 (1)	$ 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	Total
		(In thousands)	
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 (1)	(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 (1)	(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	$ 216,257

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:

	Principal	Interest	Total
		(In thousands)	
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	$ 216,257	$ 84,659	$ 300,916

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:

	December 31, 2024	December 31, 2023
	(In thousands)	
Assets		
Operating lease assets	$ 14,961	$ 18,631
Finance lease assets, net	2,025	1,220
Total lease assets	$ 16,986	$ 19,851
Liabilities		
Current:		
Operating leases	$ 5,239	$ 4,590
Finance leases	732	570
Non-current:		
Operating leases	12,224	17,424
Finance leases	1,242	719
Total lease liabilities	$ 19,437	$ 23,303
Weighted-average remaining lease term		
Operating leases (years)	2.9	3.8
Finance leases (years)	3.5	2.3
Weighted-average discount rate		
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	$ 9,164	$ 8,975

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	$ 17,463	$ 1,974	$ 19,437

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:

	December 31,	
	2024	2023
	(In thousands)	
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:

	Year ended December 31,		
	2024	2023	2022
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	$	4,463

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
Equity compensation plans approved by security holders:				
2017 Omnibus Incentive Compensation Plan (1)	13,966,710	$	7.57	6,881,912
2008 Equity Incentive Plan (2)	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. Demopulos, M.D. dated April 7, 2010	8-K	001-34475	10.1	04/12/2010
10.7*	Omeros Corporation Non-Employee Director Compensation Policy	10-K	001-34475	10.11	03/13/2023
10.8	Lease dated January 27, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	8-K	001-34475	10.1	02/01/2012
10.9	First Amendment to Lease dated November 5, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.2	11/09/2012
10.10	Second Amendment to Lease dated November 16, 2012 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.18	03/18/2013
10.11	Third Amendment to Lease dated October 16, 2013 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.18	03/13/2014
10.12	Fourth Amendment to Lease dated September 8, 2015 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.3	11/09/2015
10.13	Fifth Amendment to Lease dated September 1, 2016 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-Q	001-34475	10.1	05/10/2017
10.14	Sixth Amendment to Lease dated October 18, 2018 between Omeros Corporation and BMR-201 Elliott Avenue LLC	10-K	001-34475	10.19	03/01/2019

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

10.23	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					X

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

* Indicates management contract or compensatory plan or arrangement.

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

ITEM 16. FORM 10-K SUMMARY

Not included.

SIGNATURES

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

OMEROS CORPORATION

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

Dated: 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.

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

Exhibit 10.25

SEVENTEENTH AMENDMENT TO LEASE

THIS SEVENTEENTH AMENDMENT TO LEASE (this "Amendment") is entered into as of this 18th day of December, 2024 (the "Seventeenth Amendment Execution Date") and is effective, retroactively, as of October 1, 2024 (the "Effective Date"), by and between BMR-201 ELLIOTT AVENUE LLC, a Delaware limited liability company ("Landlord"), and OMEROS CORPORATION, a Washington corporation ("Tenant").

RECITALS

A. WHEREAS, Landlord and Tenant are parties to that certain Lease dated as of January 27, 2012 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of November 5, 2012, that certain Second Amendment to Lease dated as of November 16, 2012, that certain Third Amendment to Lease dated as of October 16, 2013, that certain Fourth Amendment to Lease dated as of September 8, 2015, that certain Fifth Amendment to Lease dated as of September 1, 2016 (the "Fifth Amendment"), that certain Sixth Amendment to Lease dated as of October 18, 2018, that certain Seventh Amendment to Lease dated as of April 15, 2019, that certain Eighth Amendment to Lease dated as of October 28, 2019, that certain Ninth Amendment to Lease dated as of January 15, 2020, that certain Tenth Amendment to Lease dated as of September 15, 2020, that certain Eleventh Amendment to Lease dated as of October 23, 2020, that certain Twelfth Amendment to Lease dated as of January 1, 2021, that certain Thirteenth Amendment to Lease dated as of June 1, 2021, that certain Fourteenth Amendment to Lease dated as of January 14, 2022, that certain Fifteenth Amendment to Lease dated as of November 1, 2022 and that certain Sixteenth Amendment to Lease dated as of July 8, 2024 (collectively, and as the same may have been further amended, amended and restated, supplemented or modified from time to time, the "Existing Lease"), whereby Tenant leases certain premises (the "Existing Premises") from Landlord at 201 Elliott Avenue West in Seattle, Washington (the "Building");

B. WHEREAS, Landlord and Tenant wish to terminate the Existing Lease with respect to the Fourth Additional Vivarium Premises (as defined in the Fifth Amendment) only;

C. WHEREAS, for clarity, the Fourth Additional Vivarium Premises are Suites 156 and 156A;

D. WHEREAS, Tenant wishes to lease certain other additional premises from Landlord in the Building's Vivarium as set forth herein; and

E. WHEREAS, Landlord and Tenant desire to modify and amend the Existing Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

1. Definitions. For purposes of this Amendment, capitalized terms shall have the meanings ascribed to them in the Existing Lease unless otherwise defined herein. The Existing Lease, as amended by this Amendment, is referred to collectively herein as the "Lease." From and after the date hereof, the term "Lease," as used in the Existing Lease, shall mean the Existing Lease, as amended by this Amendment.

2. Termination of Fourth Additional Vivarium Premises. Landlord and Tenant acknowledge and agree that (i) Tenant exercised its option to terminate the Fourth Additional Vivarium Premises (as defined in the Fifth Amendment); (ii) Landlord hereby waives the requirement that Tenant provide at least sixty (60) days' prior written notice of such termination to Landlord as set forth in Section 7.b. of the Fifth Amendment; (iii) Landlord hereby waives the requirement that Tenant surrender the Fourth Additional Vivarium Premises in the condition required under the Lease (including, without limitation, Section 18.2 and Article 26 of the Lease); and, (iv) therefore, the Fourth Additional Vivarium Termination Date (as defined in the Fifth Amendment) shall be September 30, 2024. Accordingly, from and after the Fourth Additional Vivarium Termination Date, the Lease with respect to the Fourth Additional Vivarium Premises only shall terminate and be of no further force or effect and Landlord and Tenant shall be relieved of their respective obligations under the Lease with respect to the Fourth Additional Vivarium Premises only, including any obligation on the part of Tenant to pay any Rent for the Fourth Additional Vivarium Premises (including any monthly Base Rent).

3. Twelfth Additional Vivarium Premises. Effective as of the Effective Date, Landlord hereby leases to Tenant and Tenant hereby leases from Landlord, approximately one thousand one hundred thirty-four (1,134) aggregate additional square feet of Rentable Area located collectively in Suites 158 and 158A in the Building's Vivarium, as shown on Exhibit A attached hereto (the "Twelfth Additional Vivarium Premises"), for use by Tenant in accordance with the Permitted Use and in accordance with all other terms and conditions of the Lease. From and after the Effective Date, the term "Premises," as used in the Lease shall mean the Existing Premises plus the Twelfth Additional Vivarium Premises, and the term "Tenant's Vivarium Space," as used in the Lease, shall mean the Tenant's existing Vivarium space plus the Twelfth Additional Vivarium Premises.

4. Twelfth Additional Vivarium Premises Term. The Term of the Lease with respect to the Twelfth Additional Vivarium Premises (as the same may be earlier terminated in accordance with the Lease, the "Twelfth Additional Vivarium Premises Term") shall commence on the Effective Date and shall expire on the Term Expiration Date. Failure by Tenant to obtain validation by any medical review board or other similar governmental licensing of the Twelfth Additional Vivarium Premises required for the Permitted Use by Tenant shall not serve to extend the commencement of the Twelfth Additional Vivarium Premises Term.

5. Condition of Twelfth Additional Vivarium Premises. Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the Twelfth Additional Vivarium Premises or with respect to the suitability of the Twelfth Additional Vivarium Premises for the conduct of Tenant's business. Tenant acknowledges that (a) it is fully familiar with the condition of the Twelfth Additional Vivarium Premises and agrees to take the same in its condition "as is" as of the commencement of the Twelfth Additional Vivarium Premises Term and (b) Landlord shall have no obligation to alter, repair or otherwise prepare the Twelfth Additional Vivarium Premises for Tenant's occupancy or to pay for or construct any improvements to the Twelfth Additional Vivarium Premises. Tenant's taking of possession of the Twelfth Additional Vivarium Premises shall, except as otherwise agreed to in writing by Landlord and Tenant, conclusively establish that the Twelfth Additional Vivarium Premises were at such time in good, sanitary and satisfactory condition and repair.

6. Base Rent and Additional Rent. In addition to all Base Rent for the Existing Premises, commencing on the commencement of the Twelfth Additional Vivarium Premises Term and continuing for the duration of the Twelfth Additional Vivarium Premises Term, Tenant shall pay to Landlord (in accordance with the provisions of the Lease) Base Rent for the Twelfth Additional Vivarium Premises. Base Rent (including the monthly installments of Base Rent) for the Twelfth Additional Vivarium Premises shall equal the applicable amounts set forth on Exhibit B attached hereto. In addition to all Additional Rent for the Existing Premises, commencing as of the commencement of the Twelfth Additional Vivarium Premises Term and continuing for the duration of the Twelfth Additional Vivarium Premises Term, Tenant shall pay to Landlord Additional Rent (as defined in, and in accordance with the provisions of, the Lease) with respect to the Twelfth Additional Vivarium Premises.

7. Pro Rata Share. Tenant's Pro Rata Share of the Project with respect to the Twelfth Additional Vivarium Premises shall be 0.75%. Therefore, commencing as of the commencement of the Twelfth Additional Vivarium Premises Term, Tenant's Pro Rata Share of the Project for the entire Premises (i.e., the Existing Premises plus the Twelfth Additional Vivarium Premises) shall be 74.03%.

8. Termination Option. Notwithstanding anything to the contrary in the Lease, Tenant shall have the right to terminate the Lease, but only with respect to the Twelfth Additional Vivarium Premises (and no less than all of the Twelfth Additional Vivarium Premises), by providing written notice (the "Twelfth Additional Vivarium Termination Notice") to Landlord at least sixty (60) days prior to Tenant's desired termination date (the "Twelfth Additional Vivarium Termination Date"), which Twelfth Additional Vivarium Termination Date shall be set forth in the Twelfth Additional Vivarium Termination Notice. Subject to (a) Landlord's timely receipt of the Twelfth Additional Vivarium Termination Notice and (b) Tenant surrendering the Twelfth Additional Vivarium Premises in the condition required under the Lease (including, without limitation, Section 18.2 and Article 26 of the Lease), then, as of the Twelfth Additional Vivarium Termination Date, the Lease with respect to the Twelfth Additional Vivarium Premises only shall terminate and be of no further force or effect, and Landlord and Tenant shall be relieved of their respective obligations under the Lease with respect to the Twelfth Additional Vivarium Premises only from and after the Twelfth Additional Vivarium Termination Date, except with respect to those obligations set forth in the Lease that expressly survive the expiration or earlier termination thereof, including payment by Tenant of all amounts owed by Tenant pursuant to the Lease with respect to the Twelfth Additional Vivarium Premises for the period up to and including the Twelfth Additional Vivarium Termination Date. The termination right granted to Tenant pursuant to this Section shall automatically terminate and be of no further force or effect in the event that (y) Tenant assigns, subleases or otherwise Transfers the Twelfth Additional Vivarium Premises or any portion thereof to other entities or persons, other than in connection with an Exempt Transfer (or in connection with any sublease approved by Landlord pursuant to Article 29 of the Lease), or (z) Tenant's right to possession of the Twelfth Additional Vivarium Premises has previously been terminated. The termination right granted to Tenant pursuant to this Section is personal to Omeros Corporation, a Washington corporation ("Omeros") and any Permitted Transferees of Omeros, and may not be exercised by any other assignee, sublessee or transferee of Tenant's or a Permitted Transferee's interest in the Lease.

9. Broker. Tenant represents and warrants that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment and agrees to reimburse, indemnify, save, defend (at Landlord's option and with counsel reasonably acceptable to Landlord, at Tenant's sole cost and expense) and hold harmless the Landlord Indemnitees for, from and against any and all cost or liability for compensation claimed by any such broker or agent employed or engaged by it or claiming to have been employed or engaged by it.

10. No Default. Tenant represents, warrants and covenants that, to the best of Tenant's knowledge, Landlord and Tenant are not in default of any of their respective obligations under the Existing Lease and no event has occurred that, with the passage of time or the giving of notice (or both) would constitute a default by either Landlord or Tenant thereunder.

11. Effect of Amendment. Except as modified by this Amendment, the Existing Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. In the event of any conflict between the terms contained in this Amendment and the Existing Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties.

12. Successors and Assigns. Each of the covenants, conditions and agreements contained in this Amendment shall inure to the benefit of and shall apply to and be binding upon the parties hereto and their respective heirs, legatees, devisees, executors, administrators and permitted successors and assigns and sublessees. Nothing in this Section shall in any way alter the provisions of the Lease restricting assignment or subletting.

13. Miscellaneous. This Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Amendment are inserted and included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for a lease, and shall not be effective as a lease, lease amendment or otherwise until execution by and delivery to both Landlord and Tenant.

14. Authority. Tenant guarantees, warrants and represents that the individual or individuals signing this Amendment have the power, authority and legal capacity to sign this Amendment on behalf of and to bind all entities, corporations, partnerships, limited liability companies, joint venturers or other organizations and entities on whose behalf such individual or individuals have signed.

15. Counterparts; Facsimile, Electronic and PDF Signatures. This Amendment may be executed in one or more counterparts, each of which, when taken together, shall constitute one and the same document. A facsimile, electronic or portable document format (PDF) signature on this Amendment shall be equivalent to, and have the same force and effect as, an original signature.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the date and year first above written.

LANDLORD:

BMR-201 ELLIOTT AVENUE LLC,
a Delaware limited liability company

By: /s/ Dawn Saunders
Name: Dawn Saunders
Title: Vice President, Legal

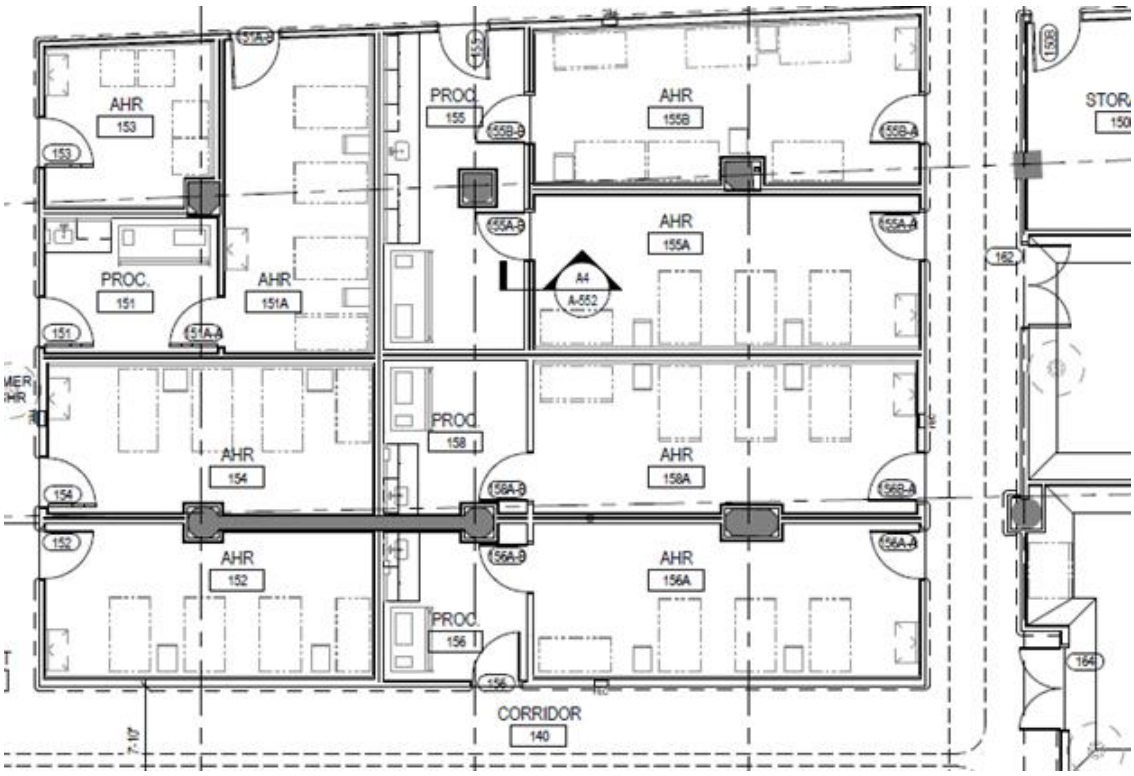
TENANT:

OMEROS CORPORATION,
a Washington corporation

By: /s/ Peter Cancelmo
Name: Peter Cancelmo
Title: VP, General Counsel

EXHIBIT A

TWELFTH ADDITIONAL VIVARIUM PREMISES



**The red highlighted areas above represent the Twelfth Additional Vivarium Premises. Landlord makes no representation or warranty with respect any items depicted in this Exhibit A (including, without limitation, any furniture, fixtures or equipment), including whether any such items currently exist within the Building or the Project.

EXHIBIT B

BASE RENT FOR TWELFTH ADDITIONAL VIVARIUM PREMISES

Dates	Square Feet of Rentable Area	Annual Base Rent per Square Foot Of Rentable Area	Monthly Base Rent
October 1, 2024-November 15, 2024	1,134	$83.05	$ 7,848.23
November 16, 2024-November 15, 2025	1,134	$85.55	$ 8,084.48
November 16, 2025-November 15, 2026	1,134	$88.11	$ 8,326.40
November 16, 2026-November 15, 2027	1,134	$90.76	$ 8,576.82

Exhibit 10.30

[***] 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.

—CONFIDENTIAL—

THIS COMBINED DEVELOPMENT AND COMMERCIAL SUPPLY AGREEMENT, made effective as of May 16, 2018 (this "Agreement"), by and between Omeros Corporation, a company duly organized and existing under the laws of Washington ("Customer"), and Vetter Pharma International GmbH, a company duly organized and existing under the laws of Germany ("Vetter"), and Customer and Vetter individually also a "Party" and collectively the "Parties",

WITNESSETH:

WHEREAS, a Confidentiality Agreement has been entered into; and

WHEREAS, Customer desires certain Development Work, including the Manufacture of liquid vials pre-filled with its OMS721 drug substance for use within the Territory, including, after successful finalization of the Development Work, for Commercial Work;

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, and subject to the terms and conditions of this Agreement, Customer and Vetter agree as follows:

ARTICLE 1: DEFINITIONS

For all purposes of this Agreement, and all amendments thereto, the following capitalized terms, whether used in the singular or plural, shall have the same and uniform meanings as below defined and specified, unless the context otherwise requires:

(1) "Actual Yield" has the meaning set forth in Section 12(3).

(2) "Affiliate" means, in respect of Customer, any person, firm, company, or entity which directly or indirectly controlled by Customer and, in respect of Vetter, any person, firm, company, or entity which is under common control of the trustees/executors of the estate of Helmut Vetter, and "control" means owning more than fifty percent (50%) of the voting stock or interests.

(3) "Agreed Process Specifications" means a set of documents listed in an Annex to the Quality Agreement containing the most current process specifications for Manufacture of Product, including testing procedures, analytical specifications and other relevant technical information, data or instructions, upon which Customer and Vetter Pharma agreed upon as provided in the applicable QA, including, but not limited to, any such part of the Product Information which Vetter Pharma and Customer agree to be relevant for and applicable to the Manufacture of the Product, which specifications may be amended from time to time by mutual agreement of Vetter Pharma and Customer in accordance with the change control procedures contemplated in the applicable QA, and which may also be referred to as "PDS" or "Process Development Specifications" for the Development Work.

(4) "Agreement" means this combined development and commercial supply agreement and its Annexes, including the QA and its Appendices.

(5) "AICC Rules" has the meaning set forth in Section 23(13)(b).

(6) "Annex" means a document, which may be titled as an annex, proposal, quotation, scope of work or similar, that references this Agreement or an annex attached to this Agreement, executed by duly authorized officials of both Parties, and which, once so executed, shall be deemed to be incorporated into this Agreement as its integral part.

(7) "Annual Cap" means, for any calendar year during the Term, the lesser amount, which shall be prorated for any part year, of (i) [***] percent ([***]%) of all net amounts paid to Vetter by Customer under this Agreement during the twelve (12)months' period prior to an event applicable hereunder; and (ii) [***] Euros, which foregoing lesser total annual amount shall be applicable aggregately, and not separately, to the liability obligations of Vetter, in a calendar year, to Customer under this Agreement, but only where and to the extent expressly set forth herein, including Sections 7(4) (API Storage Losses During Development Work), 12(3) (Yield), 14(1) (Defective Commercial Work), 14(2) (API Storage Losses During Commercial Work) and 20(4) (Recall Costs); provided, however, which lesser total annual amount (namely, the resulting Annual Cap) shall, for clarity, be unlimited in the instances addressed by Section 21(4).

(8) "API" means the active pharmaceutical ingredient, developed and owned by Customer, that is an antibody to MASP-2 and that is known by the project name OMS721.

(9) "API Delivery Date" has the meaning set forth in Annex 4.

(10) "API Invention" has the meaning set forth in Section 19(2).

(11) "API Value" means the mutually agreed contractual value of the API, which shall be [***] percent ([***]%) of Vetter's price of a commercial batch of the Product, for the API contained in such batch, except in the instances addressed by Section 21(4), in which case "API Value" means Customer's full replacement cost of the API.

(12) "Appendix" means an appendix attached to the QA.

(13) "Article" means an article of this Agreement (excluding the QA).

(14) "Assignee" has the meaning set forth in Section 23(8).

(15) "Assistance" has the meaning set forth in Section 18(8).

(16) "Business Day" means any calendar day other than a Saturday, a Sunday or a calendar day on which commercial banks located in Baden-Württemberg, Germany, or at the principal place of business of Customer, as applicable to the Party needing to take action, are authorized or required by law to be closed.

[***] 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.

(17) "Commercial Forecast" has the meaning set forth in Annex 4.

(18) "Commercial Work" means the work related to the Manufacture of Product intended by Customer for commercial purposes; provided, however, for clarity, the Manufacture of Product resulting from successful process verification shall be part of the Development Work, but the performance of such Product in the market shall be governed by the provisions hereof applicable to the Commercial Work.

(19) "Completion Date" has the meaning set forth in Section 22(1).

(20) "Confidential Information" has the meaning set forth in the Confidentiality Agreement.

(21) "Confidentiality Agreement" means the confidentiality agreement effective as of April, 24, 2015, as amended as of June 1, 2017, between Customer, Vetter and/or any of its Affiliates, as the case may be.

(22) "Costs" means any and all damages, liabilities, claims, suits, awards, judgments, costs and/or expenses, whether based on product liability or otherwise, including any court costs and/or reasonable attorneys' fees.

(23) "Customer" has the meaning set forth first above.

(24) "Customer Disclosed Manufacture IP" has the meaning set forth in Section 19(3).

(25) "Customer Materials" means all materials, including API and Excipients, Primary Packaging Materials or Secondary Packaging Materials (each as defined in the applicable QA), selected, specified or supplied to the Facility by Customer or on behalf of Customer in accordance with this Agreement, examples of which are specified in the applicable QA.

(26) "Delivery Date" has the meaning set forth in Section 4(1).

(27) "Development Schedule" means the work plan set forth in Annex 1, as may be amended, modified or changed from time to time by written agreement of the Parties.

(28) "Development Work" means the Manufacture work, and other work that is referred to in the Development Schedule.

(29) "Disclosed Manufacture Know-How" has the meaning set forth in Section 19(2).

(30) "Effective Date" means the day and year set forth first above.

(31) "EMA" means the European Medicines Agency, or any successor agency.

(32) "Equipment" means the equipment listed in Annex 3, to be exclusively dedicated to the Manufacture of the Product.

(33) "Facility" means the manufacturing and logistics facilities used for the Development Work and the Commercial Work that have been approved in advance by Customer, listed in the Quality Agreement and in compliance with cGMP, and located in or near Ravensburg or Langenargen, Germany.

(34) "FCPA" has the meaning set forth in Section 20(9).

(35) "FDA" means the Food and Drug Administration of the United States of America, or any successor agency.

(36) "Force Majeure" has the meaning set forth in Section 23(1).

(37) "GMP", "cGMP" or "Good Manufacturing Practices" means the following standard, in effect as of the Effective Date or as thereafter then-current at the time of the applicable Manufacturing activity being performed, as may be specified in the applicable QA, namely, the (i) European Directive 2001/83/EC, as amended (including 2011/62/EU); (ii) European Directive 2003/94/EC, as amended; (iii) EudraLex Volume 4; (iv) German Drug Act (Arzneimittelgesetz, "AMG"); (v) German Regulation on the Manufacture of Drugs and Active Substances (Arzneimittel- und Wirkstoffherstellungsverordnung, "AMWHV"); (vi) US regulations 21 CFR 4, 21 CFR 11, 21 CFR 210, 21 CFR 211; (vii) US regulation 21 CFR 600, 610 for biologic products; (viii) US regulation 21 CFR 820 for Combination Products; (ix) US regulation 21 USC 335a; and (x) ICH quality guidelines Q1A, Q1B, Q1E, Q2, Q3B, Q3C, Q3D, Q5C, Q6A, Q6B, Q8, Q9, Q10.

(38) "Grieshaber" has the meaning set forth in Section 23(8).

(39) "Information" has the meaning set forth for "Confidential Information" in the Confidentiality Agreement.

(40) "IP" has the meaning set forth in Section 19(1).

(41) "KPIs" has the meaning set forth in Annex 4.

(42) "Launch" has the meaning set forth in Annex 4.

(43) "Launch Batch" has the meaning set forth in Annex 4.

(44) "Long Range Forecast" has the meaning set forth in Section 2 of Annex 4.

(45) "Low Volume Manufacturing Phase" has the meaning set forth in the preamble of Annex 4.

(46) "Manufacture" and "Manufacturing" means the operations of Vetter Pharma or its Affiliates to manufacture the Products for and on behalf of Customer at the Facility, including, but not limited to, production, processing, filling, lyophilization, labeling, packaging, serialization, storage, sampling and testing of the Product, materials and intermediates, receipt of materials (including Customer Materials and Sourced Materials), as well as related in-process control, quality control testing, quality assurance and certification activities, the generation of stability data of Product, as the case may be, all as detailed in the Agreed Process Specifications.

(47) "Manufacture Invention" has the meaning set forth in Section 19(3).

(48) "Materials" means both, the Sourced Materials and the Customer Materials.

(49) "Parties" means Customer and Vetter, and "Party" means either thereof.

(50) "Pre-Existing IP" has the meaning set forth in Section 19(1).

(51) "Product" means a container closure or other agreed application system filled by Vetter Pharma with Customer's antibody to MASP-2 (that is referred to as API, namely the anti-MASP-2 antibody referred to by Customer as OMS721, as of the Effective Date), whether as Intermediate Product, Bulk Product or Finished Product, including samples, each as further described in the QA.

(52) "Product Information" means all information provided by or on behalf of Customer under this Agreement, including (i) the specifications and other technical requirements of the API; (ii) instructions of any kind, such as instructions related to the API during Manufacture, including handling, processing, safety, waste disposition and testing procedures; (iii) other information about the API, the Product or the Manufacture, Customer Materials and Sourced Materials, which information shall also include all information concerning the chemical and physical nature of the Materials and any components; (iv) any requirements applicable to the Product or its Manufacture, whether coming from Regulatory Approvals, Territory Laws or Product-specific GMPs.

(53) "Purchase Order" means a purchase order placed with Vetter by Customer that is duly issued by Customer and that is firm, binding and irrevocable on Customer and Vetter once confirmed by Vetter, subject only to any rescheduling or cancellation as may be permitted under, in accordance with and subject to the terms of this Agreement and Annex 4, and such purchase order shall be valid for the purpose of confirming quantities and prospective Delivery Dates of the Product.

(54) "Quality Agreement" or "QA" means the quality agreement (including all Appendices), as applicable with respect to the status of the development and commercialization of the Product, which agreement Vetter shall cause Vetter Pharma to enter into with respect to the quality of the Product, to be in effect contemporaneously with the term of the Development Work or the Commercial Work, with respect to all such activities delegated by Vetter to Vetter Pharma in respect of the Manufacture and quality of the Product, contained in a separate document attached hereto as Annex 5, and considered by the Parties and its respective Affiliates as an integral part of this Agreement.

(55) "Regulatory Approvals" means any and all approvals, consents, clearances, permissions, licenses and registrations to be obtained from from the applicable governmental authorities, and thereafter to be maintained, by Customer, in accordance with the Territory Laws, in order for Customer to have Manufactured, to use (including, but not limited to, the use by Customer in clinical trials), to register, to import, to export, to distribute, to market, to promote or to sell, the Product.

(56) "Representatives" means any Affiliate and/or any employee, officer, director and trustee/executor of a Party and/or an Affiliate.

(57) "Rolling Forecast" has the meaning set forth in Section 4(1) of Annex 4.

(58) "Section" means a subsection of an Article.

(59) "Standard" means, with respect to the Manufacture, (i) conformity with the Agreed Process Specifications, then-current GMP (unless otherwise specified in the Development Schedule), applicable SOPs and the approved master batch records; (ii) compliance with the applicable rules and regulations officially published and promulgated by the FDA or the European Commission (EMA); (iii) compliance with any and all other Territory Laws.

(60) "Standard Manufacturing Phase" has the meaning set forth in Annex 4.

(61) "SOPs" means the applicable standard operating procedures of Vetter Pharma.

(62) "Sourced Materials" means all materials, including Excipients, components and Primary Packaging Materials and Secondary Packaging Materials, selected, specified or approved by Customer and listed in the respective Agreed Process Specifications, which Sourced Materials shall be provided by Vetter Pharma on behalf of Customer, subject to the provisions of this Agreement, examples of which are specified in the applicable QA.

(63) "Target Yield" has the meaning set forth in Section 12(1).

(64) "Technical Records" has the meaning set forth in Section 18(3).

(65) "Term" has the meaning set forth in Section 22(1).

(66) "Territory" means all countries under the jurisdiction of the FDA and/or the European Commission (EMA), and any other countries or regions upon which the Parties may mutually agree in a written amendment of this Agreement.

(67) "Territory Laws" means, (i) with respect to Customer, any applicable statute, law, rule, regulation, ordinance, guideline, determination, judgment, rule of law, order, policy, decree, permit, approval, concession, grant, license, requirement, or any similar form of decision of, or any provision or condition of any permit, license or other operating authorization issued by any governmental or regulatory authority having or asserting jurisdiction over the Product, its Manufacture, the activities to be performed under this Agreement or the QA by or on behalf (other than by Vetter) of Customer, and over any registration, import, export, distribution, of the Product, in effect as of the Effective Date or as thereafter then-current at the relevant point in time, including GMP (as and when applicable); (i) with respect to Vetter, as set forth in Section 2(2) and subject thereto, (x) any cGMP of EMA and/or FDA, and any applicable German or applicable European statute, law, rule, regulation, ordinance, guideline, determination, judgment, rule of law, order, policy, decree, permit, approval, concession, grant, license, requirement, or any similar form of decision of, or any provision or condition of any permit, license or other operating authorization related to Manufacture of the Product, in effect as of the Effective Date or as thereafter then-current at the time of the applicable Manufacturing activity being performed; (y) if specifically agreed by the Parties, any applicable statute, law, rule, regulation, ordinance, guideline, determination, judgment, rule of law, order, policy, decree, permit, approval, concession, grant, license, requirement, or any similar form of decision of, or any provision or condition of any permit, license or other operating authorization, in effect as then-current at the time of the applicable Manufacturing activity being performed, related to the Manufacture of the Product, of any other jurisdiction or regulatory authority, all such other jurisdiction(s) or regulatory authority(ies) as specifically and prior to its applicability hereunder agreed to in writing by the Parties.

(68) "Transition Compensation" means the documented and reasonably justifiable costs incurred by Vetter and/or Vetter Pharma, hereunder payable by Customer to Vetter and arising directly out of any assignment or transfer of this Agreement by Customer, it being acknowledged and agreed by each Party that (i) the sole purpose for the efforts underlying such compensation is to achieve the same service and performance level with the Assignee as exists or would have existed with Customer had there been no such assignment or transfer; (ii) any work, activities (including any Facility audits), costs or price increases, which are unrelated to such effort described in clause (i), shall be independently agreed upon by Vetter and the Assignee (and the costs thereof shall not be considered Transition Compensation); (iii) such compensation may include such items as the reasonable work and related costs of personnel of Vetter and/or Vetter Pharma (including reassignments and overtime) to integrate the personnel of the Assignee and Vetter and/or Vetter Pharma with respect to the Manufacture responsibilities and management-level integration, in each case as requested by the Assignee; (iv) such compensation is not capable of being quantified before Vetter has had a reasonable opportunity to meet with and discuss the transition with the Assignee; and (v) such compensation may initially include some amount of reasonable estimation by Vetter, but that Vetter shall use commercially reasonable efforts to adjust, refine and justify such compensation as incurred over time, and in the event of an overpayment by Customer, such funds shall be refunded by Vetter to Customer without undue delay, as applicable and, for clarity, any costs or expenses arising from changes to the Development Work and/or the Commercial Work, master batch record, Agreed Process Specifications, Manufacturing process or other obligations of Vetter under this Agreement (including the Development Schedule) or the Quality Agreement requested by such Assignee (and/or separately agreed upon by Assignee and Vetter) shall not be considered Transition Compensation.

(69) "Vetter" has the meaning set forth first above.

(70) "Vetter Pharma" means Vetter Pharma-Fertigung GmbH & Co. KG, an Affiliate of Vetter duly organized and existing under the laws of Germany, having its principal place of business at Schützenstraße 87, 88212 Ravensburg, Germany.

(71) "Warehouse" means the warehousing facility of Vetter Pharma located at Helmut-Vetter-Straße 10, 88213 Ravensburg, Germany, as directed by Vetter in writing.

ARTICLE 2: GENERAL

(1) Set-Up. For the Development Work and/or the Commercial Work, Vetter shall supply the Product to Customer in accordance with the terms of this Agreement, the Manufacture being subcontracted by Vetter to Vetter Pharma and being performed by Vetter Pharma, all as set forth and more fully described in the QA. The goals of the Development Work are to (i) Manufacture batches of the Product (including intended for human use, and validation batches); (ii) define the process of Manufacture in the Agreed Process Specifications; (iii) implement such process at the Facility in a format in compliance with the Standard; (iv) deliver to Customer the resulting Product and related test results and documentation. Vetter agrees to cause Vetter Pharma to use commercially reasonable efforts in satisfying the timelines set forth in the Development Schedule and/or the Commercial Work; provided, however, that in a development project, including due to the experimental character of the Development Work, timelines and prices are reasonable estimates based on past experience, Information provided by Customer, and comparable projects which, therefore, may be revised as a direct result of changes in underlying assumptions, it being agreed and understood that no change in a quoted price by more than [***] percent ([***]%) or change in timeline by more than [***] may occur without Customer's advance written consent.

(2) Standard of Manufacture. For the Development Work and/or the Commercial Work, Vetter shall cause Vetter Pharma to Manufacture in accordance with the Standard (except for those Deviations of which Customer shall be notified in writing as set forth in the QA), and provide the respective batch documentation in accordance with the Standard. For the Development Work and/or the Commercial Work, Customer shall keep Vetter informed of any legislation, rules and regulations (and any changes thereto after the Effective Date) specific to the Product. Customer shall meet all notice and information requirements as set forth in the QA. With the exception of any gross negligence or willful misconduct by Vetter and/or any of its Representatives, and without limitation of any indemnification obligations for third party claims under, and subject to, Article 20, Vetter and/or any of its Representatives shall have no responsibility or liability with respect to the Product Manufactured as part of the Development Work and/or the Commercial Work, and be conclusively deemed not negligent (i) as long as each complies with the Standard and follows the standard manufacturing, storage and other practices used in the German pharmaceutical contract manufacturing industry in performing its respective obligations which means, among other things, that each may rely on the correctness and completeness of the Agreed Process Specifications, the Information of Customer and/or any direction by or on behalf of Customer, and compliance with these practices shall be deemed conclusively proven by the batch documentation provided in accordance with the QA; (ii) if it can be shown, by way of the batch documentation, other documents or samples of the Product, that the Product has been Manufactured in accordance with the Standard, and neither Vetter nor any of its Representatives shall have any responsibility or liability, including for lack of information or if such information should not be proper for the Manufacture, if the Product has been Manufactured in accordance with the Standard.

[***] 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.

(3) Subcontractors. Other than as expressly permitted herein with respect to Vetter Pharma and Grieshaber, for the Development Work, Vetter agrees not to subcontract any of the Manufacturing of the Product unless prior written authorization is obtained from Customer. Other than as expressly permitted herein with respect to Vetter Pharma and Grieshaber, Vetter shall not assign, subcontract, or delegate any of its responsibilities under this Agreement except as specified in the Agreed Process Specifications, without the prior written consent of Customer. Such subcontractors shall be subject to confidentiality obligations at least as stringent as provided in the Confidentiality Agreement. No subcontractor may further subcontract any responsibilities under this Agreement without the prior written consent of Customer. Vetter shall be responsible, and shall remain liable, for the performance of all of its obligations under and in accordance with this Agreement, including any obligations subcontracted to Vetter Pharma and/or Grieshaber, and for any breach or failure to perform by Vetter Pharma and/or Grieshaber. Customer shall have the right to require Vetter or Vetter Pharma, in accordance with cGMP and subject thereto, to audit and inspect all subcontractors (including, without limitation, all vendors and testing contractors) with whom Vetter may enter into agreements with respect to the performance of the services.

ARTICLE 3: MATERIALS AND EQUIPMENT DURING DEVELOPMENT

(1) General. For the Development Work and/or the Commercial Work, all Materials shall be stored, used and tested at the Facility or at a third party designated by Customer in accordance with the QA. Neither Vetter nor any of its Representatives shall have any responsibility or liability to undertake any storage, use and testing or to certify the Customer Materials and/or the Sourced Materials, during the Development Work and/or the Commercial Work, other than as set forth in the QA or the Development Schedule. With respect to any Materials (whether or not incorporated into or part of the Product), Vetter shall be responsible and liable for any testing by Vetter Pharma under the QA or the Development Schedule and, with respect to the Customer Materials, as in Article 7 set forth and subject thereto.

(2) Equipment. If any Equipment is required for the Development Work as approved in advance by Customer, in the name and on behalf of Customer, Vetter shall cause Vetter Pharma to procure the Equipment. The Equipment shall be owned and insured by Vetter Pharma as and to the extent Vetter Pharma maintains insurance for its other, comparable equipment. Vetter shall cause Vetter Pharma to maintain and operate the Equipment in accordance with the SOPs, at the cost and/or expense of Vetter (other than costs and/or expenses related to repair or replacement of the Equipment, which shall be borne by Customer; provided, however, damage to or loss of the Equipment due to negligence or willful misconduct of the Standard by Vetter Pharma shall be at the cost and/or expense of Vetter).

(3) Delivery. For the Development Work, upon prior written notice to Vetter, Customer shall timely supply and deliver or have timely supplied and delivered to the Facility, at least [***], or other lead time as may be otherwise agreed, prior to the filling date as agreed between the Parties, [***] as directed by Vetter as to place, time and quantity, free of charge and at the full risk (including during shipment) of Customer (except in an event as referred to and set forth in and subject to Section 21(4) below), including with respect to any applicable transport insurance, such quantity of the Customer Materials as required to properly undertake the necessary preparations for the Manufacture of the Product, all in accordance with the QA, and to timely perform the Development Work. Such delivery shall include all documents required for the Manufacture, including quality certificates for the Customer Materials as set forth in the QA, and, at minimum, with a certificate of analysis and a certificate of conformance, materials safety data sheet, transportation and import documents and any other documents, upon which certificates and documents Vetter and/or its Representatives may fully rely without further investigation. Vetter may have rejected any supply and delivery of the Customer Materials if any thereof was not (i) ordered by Vetter; (ii) announced within reasonable time prior thereto; (iii) accompanied by complete documentation.

(4) Use, Liability, Insurance. During the Development Work, the Customer Materials shall be used for the Manufacture and mutually agreed technology transfer activities only. The Customer Materials shall at all times remain the property of Customer. During the Development Work, Customer shall be and remain responsible and liable for the Customer Materials and the quality thereof, whether or not in the possession of Vetter Pharma; provided, however, damage to or loss of the Customer Materials under Section 3(7) due to (i) slight or normal negligence in performance of the Standard by Vetter Pharma shall be at the cost and/or expense of Vetter as respectively set forth in and subject to Section 7(4); and (ii) gross negligence or willful misconduct in performance of the Standard by Vetter Pharma shall be at the cost and/or expense of Vetter, as addressed by and subject to Section 21(4). Customer may, in its sole discretion, provide adequate all-risk insurance for the Customer Materials (whether or not included as part of the Product or otherwise), and for all shipment and storage of any thereof, in an amount and on terms satisfactory to Customer.

(5) Information Requirements. For the Development Work, Customer shall provide any and all information with respect to the Customer Materials, including, without limitation, all chemical, pharmaceutical and/or biopharmaceutical compositions thereof and, to the extent reasonably known, any impact and interaction thereof on all other materials to be used in the Manufacture. If the provision of any such information has the effect, including any result of having to take additional security or safety precautions, of increasing the costs in performing obligations under the QA or hereunder, Vetter shall inform Customer thereof and an amendment to the Development Schedule shall be executed in advance; provided, however, that any increase in cost shall not be effective unless and until mutually agreed with Customer or, if not agreed, Section 18(4) shall apply. Customer shall specifically inform Vetter if the Customer Materials require any special handling or processing.

[***] 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.

(6) Inadequate Delivery. Any delay in the Manufacture, for the Development Work, arising from inadequate delivery of the Customer Materials (whether such delay is based on inadequacy of quality, quantity, missing documents or otherwise) shall postpone any Delivery Date requested by Customer and previously confirmed by Vetter until such other date that Vetter may reasonably determine in its sole discretion, after good faith consultation of Customer, taking into account such factors as Facility capacity, other production commitments and similar business factors, and Section 8(2) shall respectively apply to any postponement of production or Delivery Date. Any inadequate delivery of Customer Materials for the Development Work, inadequate only in terms of quantity or API Delivery Date and not in respect of quality, missing documents, or otherwise, that results in Vetter being unable to run a scheduled batch in a reserved slot without violation of GMP, shall be considered a cancellation of the Development Work under the respective Purchase Order, and Vetter shall be compensated as set forth in Section 8(2); provided, however, for purposes of clarity, any such inadequate delivery with respect to quantity or API Delivery Date of Customer Materials that nevertheless permits running a batch in compliance with GMP, and for any indadequacy in API Delivery Date also in Vetter's discretion exercised in good faith with respect to its or Vetter Pharma's SOPs, shall not be considered a cancellation of the entire slot, but, rather, if such an inadequate delivery results in less than the originally reserved capacity of Vetter Pharma being used, Customer shall be responsible for payment to Vetter of compensation in the amount of a partial cancellation, based pro rata on the capacity not utilized.

(7) Surplus, Storage. For the Development Work, Vetter shall notify Customer in writing of any surplus of the Customer Materials and any such surplus shall, if not usable for the Manufacture, be disposed of, returned to Customer or otherwise handled, all as reasonably directed by and at the cost and/or expense of Customer. All Customer Materials to be used for the Development Work shall be stored at the Facility, at no cost or expense payable by Customer except if for longer than [***] after the date of release of the Customer Materials for use in Manufacture at the Facility, in which event compensation for storage separately invoiced in accordance with Vetter's standard schedule shall be due.

ARTICLE 4: PRODUCT DELIVERY DATE AND DELAYS

(1) Product Delivery. Any quantity of Product, for the Development Work and/or the Commercial Work, shall be delivered on the Business Day mutually agreed upon by the Parties or, if not mutually agreed upon, then as soon as reasonably possible on a date as Vetter shall in good faith reasonably determine, along with subsequent written notification to Customer that the Product is ready for pick-up (any foregoing date, "Delivery Date"); provided, however, Vetter may reasonably and in good faith take into account for any agreement on or determination of the Delivery Date such factors as Facility capacity, other production commitments and similar business factors.

(2) Product Delivery Delays. Customer shall be informed of any delivery delay caused by Vetter, for the Development Work and/or the Commercial Work, as soon as possible if unforeseen circumstances cause any such delay in which event Customer agrees not to unreasonably refuse a requested extension period; provided, however, Customer shall not be required to grant any extension that delays the Delivery Date to later than [***] past the originally scheduled Delivery Date. If Vetter should not be able to timely fulfill or fulfill in full a Purchase Order in accordance with the terms hereof, Vetter shall notify Customer (in writing, by email), and the Parties shall discuss, and agree in good faith on an alternative Delivery Date, such agreement not to be unreasonably withheld. Upon any such inability (other than Force Majeure) not cured within [***] of the originally scheduled Delivery Date, Customer may cancel all Purchase Orders accepted by Vetter affected by such inability, such cancellation being the sole remedy for any such delay or inability to deliver to the circumstances set forth in Section 21(4).

[***] 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.

ARTICLE 5: PICK-UP AND ASSISTANCE

(1) Product Delivery. For the Development Work, Product and Product samples shall be delivered [***], deemed delivered and ready for pick up by Customer on the Delivery Date; provided, however, Product shall not be delivered to Customer by Vetter if Product has not been released by Vetter Pharma prior to a Delivery Date, unless otherwise agreed by and between the Parties in accordance with Section 5(4). Customer shall be responsible to arrange for shipment and in-time Product pick-up, using the Vetter delivery management system which includes reserving pick-up time slots provided by Vetter.

(2) Risk. For the Development Work and/or the Commercial Work, the risk of loss of or damage to the Product, except for that caused by negligence or willful misconduct of Vetter and/or any of its Affiliates, as under this Agreement assumed by Vetter, shall pass to Customer at such time the Product is made available to a carrier of Customer on the Delivery Date, or if, for any reason, Customer fails to (i) arrange for pick-up within [***] following Vetter Pharma's notice of Product release; (ii) accept without cause delivery of any Products that Manufacture of which conformed to the Standard on the Delivery Date or thereafter when ready for pick-up; or (iii) provide appropriate instructions, documents, licenses or authorization causing Vetter's inability to deliver the Product on time; provided, however, unless Vetter agrees to store released Product for Customer after release in accordance with Vetter's storage fee schedule, at pricing which also considers that Vetter is not liable for Products which should have been already picked-up by Customer, in which case risk of loss shall not pass to Customer until the end of such agreed storage period.

(3) Product Storage. For the Development Work and/or the Commercial Work, Vetter shall cause Vetter Pharma to store the Products at the Facility, as in Section 3(1) or Section 11(7), respectively, set forth in respect of the Materials, until the Delivery Date, subject to the provisions set forth in Section 7(4) or Section 14(2), respectively, which shall be respectively applicable to the storage of Product referred to under Section 3(7). In the event of pick-up delay, for the Development Work and/or the Commercial Work, Vetter shall cause Vetter Pharma to warehouse such Product, in accordance with the mutually agreed upon storage specifications for Product; provided, however, Vetter and/or its Affiliates shall have no liability for any Products stored at the Facility due to pick-up delay (except in the event of willful misconduct or gross negligence of Vetter and/or any of its Affiliates), and Article 7 and/or Article 14 shall not apply (unless specifically separately agreed, in which event Vetter shall be liable as in this Agreement provided, and storage fees separately invoiced shall be due). Section 3(4) or Section 11(2), respectively, shall respectively apply to the Product stored due to such pick-up delay, and Customer shall not be invoiced by Vetter, for storage at the Facility of such Product not picked up timely, for a period of [***] from the date of notice of Product release or notification for pick-up and thereafter, Customer shall compensate Vetter per each month of storage thereof (to be pro-rated) in the amount of [***], the Manufacture of which has been performed in accordance with the Standard.

[***] 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.

(4) Quarantine Delivery. As an exception to Section 6(1), for the Development Work, upon prior written request of Customer, Product may be shipped before release thereof to Customer in accordance with the QA but only after conclusive sterility testing by Vetter Pharma. Any such shipment of Products shall not alter each of the Parties' respective obligations and responsibilities as to Products Manufactured under this Agreement; provided, however, should Customer use and/or commercialize any unreleased Products, Customer shall assume any and all risks and liabilities in respect of such unreleased Products until release, if released.

ARTICLE 6: INCOMING INSPECTION OF DEVELOPMENT WORK

(1) Inspection. For the Development Work, Customer shall inspect the Product and review the batch documentation without delay, but in no event later than [***] following delivery hereunder of either thereof to (being actual possession by) Customer. If the Product should not pass such inspection and/or the batch documentation should not pass such review, Customer shall promptly notify Vetter in writing. Customer shall, in accordance with the instructions of Vetter, either return the rejected batch to the Facility or dispose of the Product at the cost of Vetter if the Product has not been Manufactured in accordance with the Standard.

(2) Approval. For the Development Work, any Product and/or batch documentation not rejected as in the preceding Section described shall be deemed accepted and approved by Customer to the extent that either thereof may contain any non-latent defect. Any Product and/or batch documentation containing any latent defect shall be deemed accepted and approved, unless rejected by written notice to Vetter within a period of [***] after delivery thereof; provided, however, the foregoing shall not be construed as to limit the duration of any statutes of limitations applicable to any rights of Customer which may arise out of any latent defects fraudulently concealed or caused by gross negligence or willful misconduct of Vetter and/or any of its Affiliates. Customer shall notify Vetter in writing promptly after the discovery of any latent defect.

[***] 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.

ARTICLE 7: DEFECTIVE DEVELOPMENT PRODUCT,
API STORAGE LOSSES DURING DEVELOPMENT WORK

(1) General. If Product has been rejected, for the Development Work, subject to the provisions of Article 6, Vetter shall supply Customer with replacement Product and provide the corresponding batch documentation, either at the cost and expense of Customer, or free of charge by Vetter as set forth in and subject to Section 7(3). For the purposes of such replacement, Customer shall supply or have supplied, as set forth in Article 3, Vetter with the necessary Customer Materials; provided, however, that Vetter shall, if requested by Customer in writing, use commercially reasonable efforts to accommodate the manufacture of replacement Product with a shorter lead time , as is specified in Section 3(3).

(2) Rejection. For the Development Work, Vetter shall have no responsibility and/or liability, whether for itself or any of its Affiliates, to arrange for return or disposal of the rejected Product, and/or to supply replacement Product, at the cost and expense of Vetter, if the rejection is based either solely on the supply of Customer Materials failing to conform to the applicable specifications, or on any delay of delivery thereof as in Section 3(6) set forth and subject thereto.

(3) Vetter's Fault. To the extent that the rejection of Product, for the Development Work, is due to the slight or normal negligent failure of Vetter and/or any of its Representatives (i) to have the Product Manufactured in accordance with the Standard; and/or (ii) to provide the batch documentation in accordance with the terms hereof, Vetter shall arrange for return or disposal of the rejected Product, and supply of replacement Product, and/or provide the batch documentation in accordance with the terms hereof, at the cost and expense of Vetter if, for the purposes of such replacement, Customer has supplied, at the cost of Vetter with respect to re-delivery of the Customer Materials and otherwise free of charge as set forth in Section 3(3), the Customer Materials necessary for the Manufacture of the replacement Product; provided, however, in the event of gross negligence or willful misconduct of Vetter and/or any of its Representatives, Customer shall supply and deliver, as set forth in Article 3 [***], to the Facility the Customer Materials necessary for the re-Manufacture of such replacement Product, any such foregoing expenses limited to such amount required to compensate a typically foreseeable damage (or the amount equivalent to the foregoing in the event of failing re-Manufacture).

(4) API Storage Losses During Development Work. For the Development Work, Vetter and/or any of its Representatives shall have no responsibility or liability to Customer (or any third party on behalf of Customer, specifically including any insurer of Customer) for any loss of or damage to the Customer Materials (whether included as part of the Product or otherwise, whether before Manufacture or thereafter) once delivered to the Facility, except (i) in the case of willful misconduct or gross negligence by Vetter and/or any of its Representatives, in which exception event Vetter shall compensate Customer for such API loss by the replacement value of the API; or (ii) if Vetter and/or any of its Representatives shall have been deemed having performed in slight or normal negligence and such occurrence could not have been covered by the all-risk property insurance of Customer as referred to in Section 3(4), in which exception event the only responsibility or liability of Vetter for itself and/or any of its Representatives shall be for Vetter to compensate Customer for any such loss by [***].

[***] 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.

ARTICLE 8: PURCHASE ORDERS DURING DEVELOPMENT

(1) General. For the Development Work, Customer shall issue Purchase Orders to Vetter. Any quantity of Product for the Development Work shall be delivered on the Business Day specified by Customer in a Purchase Order approved by Vetter or, if not specified or approved, within such month as Vetter shall in good faith reasonably determine; provided, however, Vetter may take into account such factors as Facility capacity, other production commitments and similar business factors and, if any circumstance reasonably requires, Vetter may execute or cause to be executed any obligation hereunder in part, and any remainder of such obligation shall be performed without undue delay.

(2) Delays. For the Development Work, Customer may cancel or postpone any Purchase Order (or part of the volumes covered thereunder) at no cost, if notice of cancellation or postponement is received by Vetter three (3) calendar months or more in advance of the filling date. If Vetter cannot identify other use of such unused production capacity (and Vetter shall use commercially reasonable efforts to identify other options of use), Customer shall pay a cancellation fee, multiplied by the volume ordered by the cancelled or postponed Purchase Order, equal to (i) [***] percent ([***]%) of the total of Vetter's price per each Product, if cancellation or postponement is made less than three (3) calendar months but more than [***] in advance of the Delivery Date; (ii) [***] percent ([***]%) of the total of Vetter's price per each Product, if cancellation or postponement is made less than [***] but more than [***] in advance of the Delivery Date; (iii) [***] percent ([***]%) of the total of Vetter's price per each Product, if cancellation or postponement is made less than [***] in advance of the Delivery Date.

ARTICLE 9: PRICES AND PAYMENTS DURING DEVELOPMENT

(1) Prices, Adjustments. Customer shall pay to Vetter such amounts for the Development Work and/or such prices for the Product as shall be determined in accordance with Annex 2, plus any applicable taxes (e.g. VAT), customs, fees and other duties, if any. For any portion of the Development Work extending beyond a [***] duration, as of the Effective Date, Vetter may adjust its prices to reflect an increase in the costs of Vetter and/or Vetter Pharma, including, by way of example, wages, insurance, other associated or related overhead cost and/or expenses, raw materials and production costs, not to exceed in any given year of the Commercial Work, the greater of (i) [***] percent ([***]%); and (ii) [***]; provided, however, any increases in the costs of the Sourced Materials shall lead to a respective price adjustment, irrespectively of the foregoing limitations on price increases.

[***] 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.

(2) Invoices, Payments. Without undue delay, Vetter shall issue an invoice, for the Development Work, upon delivery described in Section 5(1) or Section 5(5). Payments shall be made in Euros and due [***] (receipt of readily available funds by Vetter) of the date of Vetter's e-mailing of the invoice; provided, however, that if Vetter did not deliver the invoice by e-mail to Customer on the date of the invoice, which date was a Business Day for Customer, then payment shall be due [***] as of the Business Day of receipt of the invoice by Customer. If Customer pays later than the [***] period noted above, Vetter shall be entitled to interest of the invoiced amount of [***]. Accumulated in accordance with this Article as of the time of payment due, Customer shall separately pay such interest, or may add such interest to the invoiced amount and include such with the payment by Customer.

ARTICLE 10: COMMERCIAL WORK, COMMERCIAL MANUFACTURE

(1) Performance. Vetter shall supply the Product to Customer in accordance with the terms of this Agreement, it being understood and agreed that the Manufacture of the Product shall be subcontracted by Vetter to Vetter Pharma and be performed by Vetter Pharma, all as set forth and more fully described in the Quality Agreement.

(2) Commercial Manufacture. Vetter shall cause Vetter Pharma to Manufacture the Product and provide the respective batch documentation in accordance with the Standard.

(3) Equipment. Vetter shall cause Vetter Pharma to procure the Equipment as listed in Annex 3 which Equipment shall be dedicated to and paid for by Customer; provided, however, any of the foregoing shall not apply if the Equipment that has already been procured for the Development Work under and in accordance with Section 3(2) may and can be used for the Commercial Work. The Equipment shall be owned and insured by Vetter Pharma as and to the extent Vetter Pharma maintains insurance for its other, comparable equipment. Vetter shall cause Vetter Pharma to maintain and operate the Equipment in accordance with the SOPs, at the cost and/or expense of Vetter (other than costs and/or expenses related to repair or replacement of the Equipment which shall be borne by Customer; provided, however, damage to or loss of the Equipment due to negligence or willful misconduct of the Standard by Vetter Pharma shall be at the cost and/or expense of Vetter).

(4) Subcontractors. Other than as expressly permitted herein with respect to Vetter Pharma and Grieshaber, for the Commercial Work, Vetter agrees not to subcontract any of the Manufacturing of the Product unless prior written authorization is obtained from Customer. Other than as expressly permitted herein with respect to Vetter Pharma and Grieshaber, Vetter shall not assign, subcontract, or delegate any of its responsibilities under this Agreement, except as specified in the Agreed Process Specifications, without the prior written consent of Customer. Such subcontractors shall be subject to confidentiality obligations at least as stringent as provided in the Confidentiality Agreement. No subcontractor may further subcontract any responsibilities under this Agreement without the prior written consent of Customer. Vetter shall be responsible, and shall remain liable, for the performance of all of its obligations under and in accordance with this Agreement, including any obligations subcontracted to Vetter Pharma and/or Grieshaber, and for any breach or failure to perform by Vetter Pharma and/or Grieshaber. Customer shall have the right to require Vetter or Vetter Pharma, in accordance with cGMP and subject thereto, to audit and inspect all subcontractors (including, without limitation, all vendors and testing contractors) with whom Vetter may enter into agreements in the performance of the services.

[***] 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.

ARTICLE 11: MATERIALS FOR COMMERCIAL WORK

(1) Delivery. For the Commercial Work, upon prior written notice to Vetter, Customer shall timely supply and deliver or have timely supplied and delivered to the Facility, at least [***], or other lead time as may be otherwise agreed, prior to the filling date as agreed between the Parties, [***] as directed by Vetter as to place, time and quantity, free of charge and at the full risk (including during shipment) of Customer (except as otherwise set forth in Section 21(4) below), including with respect to any applicable transport insurance, such quantity of the Customer Materials as required to properly undertake the necessary preparations for the Manufacture of the Product and to timely fulfill Purchase Orders, all in accordance with the Quality Agreement, and to timely perform the Commercial Work. Such delivery shall include all documents required for the Manufacture, including quality certificates for the Customer Materials as set forth in the Quality Agreement, and, at minimum, with a certificate of analysis and a certificate of conformance, materials safety data sheet, transportation and import documents and any other documents, upon which certificates and documents Vetter and/or its Representatives may fully rely without further investigation. Vetter may have rejected any supply and delivery of the Customer Materials if any thereof was not (i) ordered by Vetter; (ii) announced within reasonable time prior thereto; (iii) accompanied by complete documentation.

(2) Status. The Customer Materials used for the Commercial Work shall at all times remain the property of Customer. During the Commercial Work, Customer shall be and remain responsible and liable for the Customer Materials and the quality thereof, whether or not in the possession of Vetter Pharma; provided, however, damage to or loss of the Customer Materials under Section 11(7) due to (i) slight or normal negligence in performance of the Standard by Vetter Pharma shall be at the cost and/or expense of Vetter as respectively set forth in and subject to Section 14(2); and (ii) gross negligence or willful misconduct in performance of the Standard by Vetter Pharma shall be at the cost and/or expense of Vetter, as addressed by and subject to Section 21(4). Customer may, in its sole discretion, provide adequate property insurance for the Customer Materials (whether or not included as part of the Product or otherwise), and for all shipment and storage of any thereof, in an amount and on terms satisfactory to Customer.

(3) Information Requirements. For the Commercial Work, Customer shall provide any and all information with respect to the Customer Materials, including, without limitation, all chemical, pharmaceutical and/or biopharmaceutical compositions thereof and, to the extent reasonably known, any impact and interaction thereof on all other materials to be used in the Manufacture of the Product. If the provision of any such information has the effect, including any result of having to take additional security or safety precautions, of increasing the costs in performing obligations under the Quality Agreement or hereunder, Vetter shall inform Customer thereof; provided, however, that any increase in cost shall not be effective unless and until mutually agreed with Customer or, if not agreed, Section 18(4) shall apply. Customer shall specifically inform Vetter if the Customer Materials require any special handling or processing. Customer shall meet all notice and information requirements set forth herein and/or in the Quality Agreement, it being understood and agreed that neither Vetter nor any of its Representatives shall have any responsibility or liability (including if arising from lack of information or if such information should not be proper for the Manufacture), if the Product has been Manufactured in accordance with the Standard.

[***] 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.

(4) Inadequate Deliveries. Any delay in the Manufacture of the Product, for the Commercial Work, arising from inadequate delivery of the Customer Materials (whether such delay is based on inadequacy of quality, quantity or otherwise) shall postpone any Delivery Date requested by Customer and previously confirmed by Vetter until such other date that Vetter may reasonably determine in its sole discretion, after good faith consultation of Customer, taking into account such factors as Facility capacity, other production commitments and similar business factors, and, subject to Section 4(3) of Annex 4, Section 8(2) shall respectively apply to any postponement of production or Delivery Date. Any inadequate delivery of Customer Materials for the Commercial Work, inadequate only in terms of quantity or API Delivery Date and not in respect of quality, missing documents, or otherwise, that results in Vetter being unable to run a scheduled batch in a reserved slot without violation of GMP, shall be considered a cancellation of the Commercial Work under the respective Purchase Order, and subject to Section 4(4) of Annex 4, Vetter shall be compensated as set forth in Section 8(2); provided, however, for purposes of clarity, any such inadequate delivery with respect to quantity or API Delivery Date of Customer Materials that nevertheless permits running a batch in compliance with GMP, and for any indadequacy in API Delivery Date also in Vetter's discretion exercised in good faith with respect to its or Vetter Pharma's SOPs, shall not be considered a cancellation of the entire slot, but, rather, if such an inadequate delivery results in less than the originally reserved capacity of Vetter Pharma being used, Customer shall be responsible for payment to Vetter of compensation in the amount of a partial cancellation, based pro rata on the capacity not utilized.

(5) Testing. For the Commercial Work, all Sourced Materials and all Customer Materials shall be tested in accordance with the Quality Agreement. Neither Vetter nor any of its Representatives shall have any responsibility or liability to undertake any testing or to otherwise certify the Customer Materials and/or the Sourced Materials other than as set forth in the Quality Agreement. With respect to any Materials (whether or not incorporated into or part of the Product), Vetter shall be responsible and liable for any testing by Vetter Pharma under the QA and, with respect to the Customer Materials, as in Article 14 set forth and subject thereto.

(6) Use, Surplus. For the Commercial Work, the Customer Materials shall be used for the Manufacture of the Product only. Vetter shall notify Customer in writing of any surplus of the Customer Materials and any such surplus shall, if not usable for the Manufacture of the Product for the Commercial Work, be disposed of, returned to Customer or otherwise handled, all as reasonably directed by and at the cost and/or expense of Customer. Upon written request of Customer, Vetter shall provide Customer with copies of a computerized inventory list, generated in accordance with the SOPs in respect of the Customer Materials stored at the Facility, all as separately agreed by and between the Parties in writing for the Commercial Work.

(7) Storage. All Customer Materials for the Commercial Work shall be stored at the Facility, at no cost or expense payable by Customer except if for longer than [***] after the date of release of the Customer Materials for use in Manufacture at the Facility, in which event compensation for storage separately invoiced in accordance with Vetter's standard schedule shall be due.

ARTICLE 12: API YIELD FOR THE COMMERCIAL WORK

(1) Target Yield. The Parties shall evaluate and mutually determine an acceptable target yield for the use of the API during the Commercial Work (and commercial batches shall consist of not less than [***] and not more than [***] Products per batch, taking into account, among other things, fixed and flexible losses, including samples, pre-flush (forerun) volume, overfill and second in-line filter; provided, however, [***] percent ([***]%) shall be deducted therefrom, to be expressed in percent, the "Target Yield"). After the Manufacture of [***] batches of the Product (for each batch size, and each clean room, separately), without any Manufacturing process changes, the Target Yield shall be as then in good faith agreed by the Parties. Until the Target Yield is established, all losses of API, and any costs and expenses incurred in respect thereof, shall be borne by Customer, including, for clarity, for any and all of the Development Work. The Target Yield, and any determination thereof, shall not be applicable to, or take account of, any batches of the Product under the Commercial Work consisting of less than [***] or of more than [***] Products. The Target Yield shall not apply if the Manufacture of the Product under the Commercial Work has been halted or interrupted for extended time period(s) or if, in any calendar year, less than [***] commercial batches of Products shall be or have been Manufactured. For clarity, the Target Yield shall only apply to, and only be deemed valid for, batch sizes between [***] and [***] Products per batch, and for any other batch sizes outside of such foregoing range, the Target Yield shall have to be mutually agreed upon and re-established for other batch sizes.

(2) Annual Review. For the Commercial Work, the Target Yield shall be reviewed, and an update thereof may be agreed by Parties from time to time through good faith negotiations, taking into account the previous performance, process enhancements, improvements and changes, GMP, SOPs and all other relevant circumstances, it being understood and agreed by the Parties that such previous performance shall not be determinative and shall not set any precedence for such review, good faith negotiations, and agreement. The Parties shall, after the end of each calendar year during the Commercial Work, mutually determine and agree on the total actual losses of API in that calendar year and on the actual yield of the API used for the Manufacture of the Product in said calendar year, "Actual Yield").

[***] 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.

(3) Reimbursement. For the Commercial Work, to the extent that the Actual Yield is equal to, or greater than, the Target Yield, all losses of API, and all costs and expenses incurred in respect thereof, shall be borne by Customer. If the Actual Yield should be less than the Target Yield, Vetter shall reimburse Customer for [***].

ARTICLE 13: INCOMING INSPECTION DURING COMMERCIAL WORK

(1) Inspection. For the Commercial Work, Customer shall inspect the Product and review the batch documentation without delay, but in no event later than [***] following delivery hereunder of either thereof. If the Product should not pass such inspection and/or the batch documentation should not pass such review, Customer shall promptly notify Vetter in writing. Customer shall, in accordance with the instructions of Vetter, either return the rejected batch to the Facility or dispose of the Product at the cost of Vetter if the Product has not been Manufactured in accordance with the Standard.

(2) Acceptance. For the Commercial Work, any Product and/or batch documentation not rejected as in the preceding Section described shall be deemed accepted and approved by Customer to the extent that either thereof may contain any non-latent defect. Any Product and/or batch documentation containing any latent defect shall be deemed accepted and approved, unless rejected by written notice to Vetter within a period of [***] after delivery thereof; provided, however, the foregoing shall not be construed as to limit the duration of any statutes of limitations applicable to any rights of Customer which may arise out of any latent defects fraudulently concealed or caused by gross negligence or willful misconduct of Vetter and/or any of its Affiliates. Customer shall notify Vetter in writing promptly after the discovery of any latent defect.

(3) Standard. Except for those Deviations (as such term is defined in the Quality Agreement) of which Customer shall be notified in writing and which shall be addressed as set forth in the Quality Agreement, all Product made available to Customer for delivery in accordance with Section 16(1) shall have been Manufactured in accordance with the Standard; provided, however, Vetter and/or any of its Representatives shall be conclusively deemed not negligent if it can be conclusively shown, by way of the batch documentation, other documents or samples of the Product, that the Product has been Manufactured in accordance with the Standard.

ARTICLE 14: DEFECTS AND LOSSES DURING COMMERCIAL WORK

(1) Defects. (a) General. If Product has been rejected, for the Commercial Work, subject to the provisions of Article 13, Vetter shall supply Customer with replacement Product and provide the corresponding batch documentation, either at the cost and expense of Customer, or free of charge by Vetter as set forth herein below and subject thereto, and shall dispose of the defective Product or send samples thereof to Customer or Customer's designee for inspection, as directed by Customer. For the purposes of such replacement, Customer shall supply or have supplied, as set forth in Article 11, Vetter with the necessary Customer Materials.

[***] 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.

(b) Rejection. For the Commercial Work, Vetter shall have no responsibility and/or liability, whether for itself or any of its Affiliates, to arrange for return or disposal of defective Product, and/or to supply replacement Product, at the cost and expense of Vetter, if the rejection is based either solely on the supply of Customer Materials failing to conform to the applicable specifications, or on any delay of delivery thereof as in Section 11(4) set forth and subject thereto.

(c) Vetter's Fault. To the extent that the rejection of Product, for the Commercial Work, is due to the slight or normal negligent failure of Vetter and/or any of its Representatives (i) to have the Product Manufactured in accordance with the Standard; and/or (ii) to provide the batch documentation in accordance with the terms hereof, Vetter shall arrange for return or disposal of the rejected Product, and supply of replacement Product, and/or provide the batch documentation in accordance with the terms hereof, at the cost and expense of Vetter if, for the purposes of such replacement, Customer has supplied, at the cost of Vetter with respect to re-delivery of the Customer Materials and otherwise free of charge as set forth in Section 11(1), the Customer Materials necessary for the Manufacture of the replacement Product; provided, however, (i) in the event of gross negligence or willful misconduct of Vetter and/or any of its Representatives, Vetter shall arrange for return or disposal of the rejected Product, and supply of replacement Product, and/or provide the batch documentation in accordance with the terms hereof, [***] and Customer shall supply and deliver, as set forth in Article 11 [***], to the Facility the Customer Materials necessary for the re-Manufacture of such replacement Product, any such foregoing expenses limited to such amount [***]; (ii) in all cases other than the foregoing gross negligence or willful misconduct of Vetter and/or any of its Representatives, Vetter shall also arrange for return or disposal of the rejected Product, and supply of replacement Product, and/or provide the batch documentation in accordance with the terms hereof, [***] and Customer shall supply and deliver, as set forth in Article 11 [***], to the Facility the Customer Materials necessary for the re-Manufacture of such replacement Product, any such foregoing expenses limited to such amount [***] but Vetter's liability in respect of lost API as part of rejected Product shall be limited as follows, [***].

[***] 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.

(2) API Storage Losses During Commercial Work. For the Commercial Work, Vetter and/or any of its Representatives shall have no responsibility or liability to Customer (or any third party on behalf of Customer, specifically including any insurer of Customer) for any loss of or damage to the Customer Materials (whether included as part of the Product or otherwise, whether before Manufacture or thereafter) once delivered to the Facility, except (i) in the case of willful misconduct or gross negligence by Vetter and/or any of its Representatives, in which exception event Vetter shall compensate Customer for such API loss by [***]; or (ii) if Vetter and/or any of its Representatives shall have been deemed performing in slight or normal negligence and such occurrence could not have been covered by the all-risk property insurance of Customer as referred to in Section 11(2), in which exception event the only responsibility or liability of Vetter for itself and/or any of its Representatives shall be for Vetter to compensate Customer for any such loss by [***].

ARTICLE 15: FORECAST AND PURCHASE ORDERS
DURING COMMERCIAL WORK

(1) Forecasts. The Long Range Forecasts, the Commercial Forecasts and the Rolling Forecasts to be provided hereunder shall be provided by Customer in accordance with and subject to Annex 4.

(2) Purchase Orders. Purchase Orders shall be provided to Vetter by Customer in accordance with Annex 4. Any quantity of Product for the Commercial Work shall be delivered on the Business Day specified by Customer in a Purchase Order approved by Vetter or, if not specified, within such month as Vetter shall in good faith reasonably determine; provided, however, Vetter may take into account such factors as Facility capacity, other production commitments and similar business factors and, if any circumstance reasonably requires, Vetter may execute or cause to be executed any obligation hereunder in part, and any remainder of such obligation shall be performed without undue delay, as set forth in and subject to the provisions of Annex 4.

ARTICLE 16: DELIVERY OF COMMERCIAL WORK

(1) Delivery. For the Commercial Work, Product shall be delivered [***], deemed delivered and ready for pick up by Customer on the Delivery Date; provided, however, Product shall not be delivered to Customer by Vetter if Product has not been released by Vetter Pharma prior to a Delivery Date, unless otherwise agreed by and between the Parties in accordance with Section 16(3). Customer shall be responsible to arrange for shipment and in-time Product pick-up, using the Vetter delivery management system which includes reserving pick-up time slots provided by Vetter.

(2) Warehousing. For the Commercial Work, if Customer should be obligated in accordance with [***] to reimburse Vetter for any costs and/or expenses incurred for warehousing of the Product at the Warehouse, Customer shall be separately invoiced by Vetter.

[***] 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.

(3) Quarantine shipment. For the Commercial Work, Product may be shipped under quarantine upon prior written request of Customer, which request shall constitute conclusive evidence that (i) Product shall be deemed delivered hereunder and ready for pick up by Customer notwithstanding anything to the contrary in this Article contained; and (ii) Customer shall hereby assume any and all risks and responsibilities associated with such quarantine shipment.

ARTICLE 17: PRICES AND PAYMENTS FOR COMMERCIAL WORK

(1) Prices, Adjustments. For the Commercial Work, Customer shall pay to Vetter such prices for the Product as shall be determined either in accordance with Annex 2 or as set forth in a quotation provided by Vetter and agreed by Customer, plus any applicable taxes (e.g. VAT), customs, fees and other duties, if any. In furtherance of Section 9(1), Vetter may adjust its prices on an annual basis to reflect an increase or decrease in the costs of Vetter and/or Vetter Pharma, including, by way of example, wages, insurance, other associated or related overhead cost and/or expenses, raw materials and production costs, not to exceed in any given year the greater of (i) [***] percent ([***]%); and (ii) [***].

(2) Payments. Without undue delay, Vetter shall issue an invoice upon delivery described in Article 16. Payments shall be made in Euros and due [***] (receipt of readily available funds by Vetter) of the date of Vetter's e-mailing of the invoice; provided, however, that if Vetter did not deliver the invoice by e-mail to Customer on the date of the invoice, which date was a Business Day for Customer, then payment shall be due [***] as of the Business Day of receipt of the invoice by Customer. If Customer pays later than the [***] period noted above, Vetter shall be entitled to interest of the invoiced amount of [***]. Accumulated in accordance with this Article as of the time of payment due, Customer shall separately pay such interest, or may add such interest to the invoiced amount and include such with the payment by Customer.

ARTICLE 18: APPROVALS, AUDITS AND CHANGES, IMPORTER OF RECORD AND INVENTORY INSPECTIONS, ASSISTANCE, ROOT CAUSE ANALYSIS

(1) Approvals. For the Development Work and/or the Commercial Work, Customer shall obtain and maintain, at its cost and risk, all Regulatory Approvals for the Development Work. Customer shall not distribute or otherwise use the Product without first securing such Regulatory Approvals. Vetter shall cooperate and make every commercially reasonable effort, at the cost and/or expense of Customer, in having information and other assistance provided as Customer may reasonably request with respect to the Regulatory Approvals. Vetter shall cause Vetter Pharma to obtain and maintain the necessary manufacturing authorization with respect to the Facility issued by the applicable German health authority in accordance with the German Medical Act (Arzneimittelgesetz) and, upon written request of Customer, Vetter shall make available a copy of such authorization. Customer understands and agrees that certain regulatory authorities may still have to approve of the Manufacture, which costs and/or expenses whereof shall be borne by Customer, and that neither Vetter nor any of its Affiliates warrants to Customer any such approval.

[***] 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.

(2) Audits. Any costs and/or expenses associated with any audits performed by any regulatory authority with respect to the Facility, the Development Work, the Commercial Work and/or the Product, shall be borne by Customer, except costs incurred from audits by the German health authorities, FDA and/or EMA not directly related to the Product which shall be borne by Vetter and for costs incurred for audits resulting from Vetter's failure to comply with the Standard in Manufacturing the Product.

(3) Technical Records. For the Development Work and/or the Commercial Work, Vetter and/or any of its Representatives shall maintain complete, true and accurate records with respect to the Manufacture of the Product (herein, "Technical Records") in accordance with Territory Laws and as is reasonably necessary to support Customer's regulatory filings with respect to Product. Vetter shall store all Technical Records for the shorter time of (i) a period of at least [***] from the relevant Product Manufacturing date; and (ii) the period required under Territory Laws, after which Vetter may dispose of the Technical Records, after providing Customer with notice as set forth in this Section, or return the Technical Records (excluding SOPs and any Confidential Information of Vetter) to Customer in accordance with Customer's express written instructions therefore. In the absence of such advance instructions, prior to any destruction of Technical Records,Vetter shall notify Customer in writing of Vetter's intent to dispose of the Technical Records and request Customer's instructions as to their disposal. If Customer does not respond to such notice within sixty (60) days after receipt thereof, or in any event prior to the later destruction of such records, Vetter may destroy such records at Customer's discretion and expense. Vetter shall, at any time upon Customer's written request and at Customer's expense, return the Technical Records to Customer or transfer the Technical Records to any third party designated by Customer.

(4) Changes. For the Development Work and/or the Commercial Work, any and all changes shall be processed in accordance with the change control procedures set forth in the QA, subject to this Section. With respect to any change to be made in accordance with the QA, Vetter and Customer shall also mutually agree on any necessary or desired amendments to this Agreement, including, without limitation, any resulting price adjustments, and any related compensation or reimbursements, as the case may be, for any additional or reduced costs, efforts and/or expenses. In the event of a controversy, claim or dispute regarding a change, Customer and Vetter shall discuss in good faith how to proceed; provided, however, Customer shall not be obligated to pay for continued Development Work (subject to Section 8(2) above) and/or the Commercial Work (subject to Section 15(2) above), which may respectively be immediately suspended at Customer's request, until any resulting price adjustments are mutually agreed; provided, further, however, Vetter shall not be required to cause Vetter Pharma to continue the Development Work and/or the Commercial Work, which may be immediately ceased, by Vetter or its Representatives based on Vetter's decision without being deemed in breach of this Agreement if Vetter as the deciding Party believes that such incorporation or non-incorporation of such change constitutes a violation of any Territory Laws. If Vetter and Vetter Pharma believe such incorporation or non-incorporation of a change does not constitute a possible violation as in the preceding sentence set forth (in which event the provisions of the immediately preceding sentence shall prevail), but creates an increased risk that Vetter and/or any of its Representatives is or could be held responsible or liable for any third party claim with respect to the Product, then Vetter shall cause Vetter Pharma to continue the Development Work and/or the Commercial Work without the incorporation or the non-incorporation of such change, in which event Customer shall indemnify, defend and hold Vetter and/or any of its Representatives harmless from and against any and all Costs resulting from or arising out of such increased risk, except for such Costs arising from Vetter or Vetter Pharma's negligence or willful misconduct in either of which exception events Articles 20 and 21 shall apply.

[***] 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.

(5) Import. With respect to importation of the Customer Materials from a country outside of the European Union, for the Development Work and/or the Commercial Work, of which Vetter shall be notified at least two (2) Business Days prior to each and every import, Vetter shall act as the importer of record for the Customer Materials. Customer shall procure that Vetter Pharma shall have the right to audit the production of the API. Vetter shall be responsible for customs' clearance of the Customer Materials and Vetter shall pay in advance the related importation value added tax on behalf of Customer if Vetter received the invoice two (2) calendar days in advance in the event of third party delivery. Vetter shall recover such tax as part of its ongoing business activities as directly attributable to the taxable services that Vetter supplies to Customer. Customer shall pay Vetter a [***] for such advance payment of the associated tax and related efforts and Customer shall provide any information and documents as may be required by Vetter in respect of any thereof or as may be required by law, including the replacement value of all Customer Materials.

(6) Inventory. Upon written request of Customer, Vetter shall provide Customer on the final Business Day of each calendar month, with copies of a computerized inventory list, generated in accordance with the SOPs, in respect of the Customer Materials stored at the Facility and to be used for the Commercial Work, all as separately agreed by and between the Parties in writing. Customer may choose, upon prior written notice, to perform an inventory inspection only once (1) in a calendar year, or more frequently for cause, upon such date as may be mutually agreed upon (and Vetter shall bear any costs thereof if not in excess of [***] of inspection by camera displaying the batch bar code, such costs including, but not limited to, such of Vetter Pharma personnel), and based on said computerized inventory list, Customer shall within such prior notice, indicate which specific pallets (of Product Manufactured for, or Customer Materials intended to be used for, the Commercial Work) are intended to be checked, on a random basis and during normal business hours; provided, however, (i) any such inventory inspection shall not exceed a total of [***] without charge; (ii) any inspection in excess of [***] and, especially, a physical inventory inspection (and not only by camera displaying the batch bar code) of all Products shall be reasonably accepted by Vetter in writing, against payment of compensation by Customer and upon prior mutual agreement between the Parties clarifying the other conditions thereof. The Parties shall mutually agree on inspection schedules and members of the inspection team, which members of Customer's inspection team shall explicitly be bound by and be subject to the Confidentiality Agreement, as modified under Section 23(2). The inspection team of Customer shall at all times be accompanied by members of Vetter's personnel, and not be divided into sub-teams. Any inventory inspection shall be conducted in accordance with GMP.

[***] 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.

(7) Audits by Customer. (a) Regular. At the cost and/or expense of Customer, with the following being subject to the Quality Agreement, Vetter shall cause Vetter Pharma to permit up to three (3) persons, of Customer's personnel and/or authorized representative(s), or Vetter shall cause Vetter Pharma to ensure that up to three (3) persons, of Customer's personnel and/or authorized representative(s), shall be entitled, (i) to inspect, observe and audit the Manufacturing of Product and the Facility; (ii) to examine the condition of the Materials and Product stored at the Facility; and (iii) to examine all Product data, Technical Records and all other documentation related to this Agreement, including maintenance logs for the purposes of ensuring compliance with the Standard and Confidential Information related to the Manufacturing of Product by Vetter Pharma hereunder, not to exceed once in any twelve (12)-months' period (except more frequently for cause) during the Term, subject to at least sixty (60) days' notice and prior approval by Vetter, such approval not to be unreasonably withheld, during regular business hours, and for a period not to exceed two (2) Business Days; provided, however, the foregoing limitations on number of personnel, notice period and audit duration shall not apply to for-cause audits; and, provided, however, further, that such three (3) persons, of Customer's personnel and/or authorized representative(s), shall be bound to obligations of confidentiality pursuant to the Confidentiality Agreement or pursuant to a separate, executed confidentiality agreement that imposes similar obligation of confidentiality. Notwithstanding these limitations, up to three (3) persons, of Customer's personnel and/or representatives, shall be entitled to observe the Manufacturing of the Product during the Development Work and during the Commercial Work, at any time (except for night shifts), upon reasonable notice and for a reasonable duration during regular business hours.

(b) For Cause. With the following being subject to the Quality Agreement, Customer shall be entitled to conduct for-cause-audits following issuance of Form 483s or similar reports delivered by Regulatory Authorities to Vetter Pharma pertaining to the Manufacturing of the Product or the occurrence of other events which are likely to adversely affect the Manufacture of the Product, as frequently as requested by Customer at reasonable times and for reasonable duration (which may exceed two (2) Business Days) until Vetter Pharma has corrected such deficiencies, subject to Vetter Pharma's approval, such approval not to be unreasonably withheld. Vetter Pharma shall audit permitted subcontractors and suppliers for compliance with the Standard, including cGMP according to Vetter Pharma's standard subcontractor audit procedures, if the subcontractors are chosen by Vetter. Customer shall be responsible for audit of all subcontractors and suppliers that have been selected by Customer, irrespectively of subcontractors and suppliers recommended or routinely used by Vetter Pharma as mentioned herein.

(8) Shipments. For the Development Work and/or the Commercial Work, and in amplification of the provisions with respect to [***] set forth or referred to above, and not in limitation thereof, Vetter shall, directly or indirectly through its Affiliates or through external service providers, upon written request of Customer and in any event at the cost and risk of Customer, provide certain assistance, details of which may be set forth in a separate written agreement, including, but not limited to (i) addressing special shipping requirements; (ii) obtaining licenses, official authorizations, clearances, customs, any other documents and/or information, including security related information that Customer may require for export, import (including import of the Customer Materials, as in Section 18(4) set forth) or transport of the Product to the final destination; (iii) making a contract for transport and/or insurance; (iv) loading the packed Product in any container, collecting vehicle or other means of transport; (v) managing sample storage (using a centrally controlled and monitored access system) and shipment, data logging, shipment and storage under, and constant monitoring of, certain temperature conditions (any and all of the above collectively, including as otherwise in this entire Article 18 referred to, "Assistance"). Customer shall, upon request of Vetter, provide information required for taxation or reporting purposes in respect of export of the Product.

(9) Root Cause Analysis. If, during any calendar quarter of the Development Work and/or the Commercial Work, two (2) or more batches should have been rejected by Customer, Vetter shall notify Customer and upon receipt of such notification by Customer, the Parties shall meet to discuss, evaluate and analyze the reasons for and implications of the failure of the Manufacture to meet the Agreed Process Specifications and the rejection by Customer and, further, Vetter shall have the right to cause Vetter Pharma to cease further Manufacturing without being deemed in default or breach under this Agreement, with all scheduled or other Manufacture not to recommence, without being in breach of this Agreement, until such time as the final disposition of the rejected batches has been determined, and complete investigations have been finalized (with root cause analysis and corrective actions) to prevent any further batch rejections, which determinations shall be agreed to in writing by the Parties, and Vetter shall perform or have performed by Vetter Pharma such investigations, root cause analysis and corrective actions diligently and expeditiously, but Customer may request in writing recommencement of the Manufacture prior to such final disposition, with and subject to Customer's assumption of responsibility in the event of further batch rejection for the same exact or similar reasons.

(10) Product Complaints. Customer shall maintain customer complaint and adverse event files in accordance with the Territory Laws. Any Product complaints or reports of adverse events received by Vetter or Vetter Pharma shall be forwarded to Customer without undue delay. Customer shall be responsible for the review of the complaint or adverse event to determine the need for an investigation or the need to report to the FDA or EMA or as required by Territory Laws. Customer shall provide Vetter with copies of all Product performance or Manufacturing-related complaints that relate directly to Manufacturing of Product by Vetter Pharma and that require investigation, as well as copies of the results of such investigation. Vetter shall cooperate and assist Customer in any such investigations and shall fully report findings of any investigation Vetter Pharma conducts with respect hereto, to Customer. Customer shall make specific complaint and adverse event files available for inspection, to the extent required by any Regulatory Authority, during inspection of the Facility.

[***] 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.

ARTICLE 19: INTELLECTUAL PROPERTY

(1) Pre-Existing IP. Except as granted under this Agreement, either Party and/or any of its Representatives shall not acquire any right, title or interest in any and all intellectual property, including any invention, patent, trademark, copyright, industrial design, trade secret, know-how and any other intellectual property, whether patentable, registered or otherwise (individually and collectively, "IP") of the other Party and/or any of its Representatives. Any right, title or interest in and to such IP existing prior to the Effective Date (respectively, "Pre-Existing IP") shall not in any way be affected by this Agreement.

(2) API Inventions, Disclosed Manufacture Know-How. Any invention, improvement, enhancement or alike made and conceived, reduced to practice and/or generated during the Term that is directed solely or primarily related to the API or production or processing of the API or the dosage form of the API ("API Invention"), but excluding any such invention, improvement, enhancement that is directed to Materials other than the API unless used in combination wth the API, shall be owned by Customer, without any restrictions, including the right to assign, transfer and sublicense, subject to any applicable German laws with respect to inventions made by employees of Vetter; provided, however, that Vetter shall secure for Customer, at the prior agreed cost and/or expense of Customer, from any such employees any rights to such API Invention held by such employees. Customer shall continue to own its IP with respect to the Manufacture (including any manufacturing process and methods) disclosed to Vetter and/or any of its Representatives and made, conceived, reduced to practice and/or generated during the Term independently of any Manufacture Invention, Confidential Information and/or Pre-Existing IP of Vetter and/or any of its Representatives, as implemented at the Facility ("Disclosed Manufacture Know-How").

(3) Manufacture Inventions. Any invention, improvement, enhancement or alike made, conceived, reduced to practice and/or generated during the Term in respect of any manufacturing process other than any API Invention or any Disclosed Manufacture Know-How ("Manufacture Invention"), shall be owned by Vetter or any of its Affiliates, without any restrictions, including the right to assign, transfer and sublicense, subject to any applicable German laws with respect to inventions made by employees of Customer.

(4) Licenses. Vetter and/or any its Affiliates shall grant Customer, subject to the terms of this Agreement, a royalty-free, fully paid up and non-exclusive license (for clarity, under any Pre-Existing IP owned by Vetter and any Manufacture Invention, with respect to the Product as a tangible object only) as may be needed solely for the sale, distribution and/or other use in non-clinical studies, in clinical trials, and commercially, within the Territory, of the Product (as a tangible object) Manufactured at the Facility, it being agreed and understood that any contribution by Vetter hereunder may not be used by Customer other than as herein provided and, specifically, that Customer may not produce and may not to have produced the Product at a location other than the Facility. Customer shall grant Vetter and/or its Affiliates a worldwide, royalty-free, fully paid up, non-exclusive and non-transferable license during the Term to perform and have performed the Manufacture of the Product for Customer, to provide and have provided the Development Work and/or the Commercial Work for Customer and to supply and have supplied the Product under this Agreement. Only to the limited extent as such Disclosed Manufacture Know-How has been used and implemented at the Facility upon the request of Customer (it being understood that the execution of this Agreement and such request also trigger the applicability of this Section) and as may be necessary to enable Vetter to provide customary development and manufacturing services to its other customers for products other than the Product and that do not contain the API, Customer shall grant Vetter and/or any of its Affiliates a perpetual, worldwide, royalty-free, fully paid up, non-exclusive and non-transferable license under any Disclosed Manufacture Know-How, as embodied in the products as may be developed and produced by Vetter and/or its Affiliates for sale, distribution and/or other use by such other customers.

ARTICLE 20: LIABILITY, INDEMNIFICATION, INSURANCE, RECALL, AND REPRESENTATIONS AND WARRANTIES

(1) Liability, Indemnification. (a) By Vetter. Except as provided in Section 21(4) or otherwise as expressly set forth herein, Vetter's liability for Vetter itself and/or any of its Representatives arising out of this Agreement shall be limited such that Vetter shall only be responsible and liable, for itself and/or any of its Representatives, for such amount required to compensate for typically foreseeable damage directly resulting from the breach by Vetter or any of its Representatives of this Agreement, subject to Section 21(1). Vetter shall indemnify, defend and hold Customer harmless from and against any and all Costs resulting from or arising out of (i) any third party claim that any manufacturing process owned and used hereunder by Vetter and/or any of its Representatives infringes any IP of any third party under the patent or intellectual property laws of the United States of America and/or the European Union or any member state thereof, up to a maximum aggregate amount of [***] Euros during the Development Work and/or the Commercial Work; (ii) any product liability claim resulting from or arising out of any slight or normal negligence of Vetter and/or any of its Representatives, up to [***] Euros in the aggregate per each calendar year during the Term (and above such amount, Section 20(2)(b) shall apply); (iii) any product liability claim resulting from or arising out of gross negligence or willful misconduct or fraud of Vetter and/or any of its Representatives, which shall not be limited.

(b) Liability Standard. For clarity, and notwithstanding anything above or below herein, Vetter shall be responsible and liable for any willful misconduct or gross negligence of Vetter and/or its Representatives in unlimited amounts. Vetter and/or any of its Representatives shall not be deemed negligent as long as each follows ths Standard, the Territory Laws and the standard manufacturing, storage and other practices used in the German pharmaceutical contract manufacturing industry in performing its respective obligations which means, among other things, that each may rely on the correctness and completeness of the Agreed Process Specifications, the Information of Customer and/or any other Information or direction by or on behalf of Customer, and compliance with these practices shall be deemed conclusively proven by the batch documentation provided in accordance with the Quality Agreement.

[***] 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.

(2) Indemnification. (a) Mutual. Each Party shall indemnify, defend and hold the other Party and/or any of its Representatives, harmless from and against any and all Costs suffered as a result of a claim of any third party (excluding Representatives), whether based on product liability or otherwise, resulting from or arising out of any negligence or willful misconduct by a Party and/or any of its Representatives, as the case may be, or breach of any of its representations, warranties, agreements or other obligations hereunder or in connection herewith.

(b) By Customer. In amplification of the foregoing, if the Product has been Manufactured and delivered in accordance with the Standard, Customer shall indemnify, defend and hold Vetter and/or any of its Representatives harmless from and against any and all Costs based on product liability, which may nevertheless be resulting from such Manufacturing. Except as provided in Section 20(1)(a), Customer shall indemnify, defend and hold Vetter and/or any of its Representatives harmless from and against any and all Costs, whether based on product liability or otherwise, resulting from or arising out of compliance by Vetter and/or any of its Representatives with the Agreed Specifications, the Information of Customer and/or any other Information or direction by or on behalf of Customer, and/or the sale, distribution and/or other use of the Product.

(c) Infringement. Except as provided in sub-clause (i) of the second sentence of Section 20(1)(a) with respect to any manufacturing process owned and used hereunder by Vetter and/or any of its Representatives, Customer shall indemnify, defend and hold Vetter and/or any of its Representatives harmless from and against any and all Costs resulting from or arising out of any Assistance or any third party claim that the Customer Materials, any Information of Customer, other matter provided by Customer, or the use by Vetter and/or any of its Representatives of any thereof, infringes any IP of any third party.

(3) Procedure, Insurance. Each Party shall promptly notify the other Party in writing of any claim, suit or other action brought or threatened in connection with or under this Agreement and shall provide reasonable cooperation in the defense of any thereof. Each Party shall not settle or otherwise resolve any such claim, suit or other action without prior written consent of the other Party. Customer shall be qualified to self-insure or maintain product liability insurance coverage with a qualified insurer with an A.M. Best rating of A-VIX, of at least (i) prior to the commercial sales launch of Product, [***] dollars per calendar year; or (ii) upon and following the commercial sales launch of Product, [***] dollars per each calendar year, which can be achieved through a combination of primary and excess product liability, during the Term. Vetter shall maintain and shall cause Vetter Pharma to maintain product liability insurance coverage (to the extent commercially reasonable and practicable and if otherwise, Vetter shall remain responsible and liable for such coverage herein set forth) with a reputable insurance company, in the aggregate of [***] Euros per each calendar year during the Term, which coverage shall include (namely be reduced by) attorneys' fees and/or court fees. Upon request of the other Party, each Party shall provide reasonable documentation and certificates to confirm that such insurance coverage is in effect.

[***] 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.

(4) Recalls. If any Product is recalled by Customer and/or by order of any regulatory authority, Vetter and/or any of its Representatives shall have no responsibility or liability with respect to any costs and/or expenses resulting from or arising out of any such recall, unless such recall is based solely on the slight or ordinary negligent failure of Vetter and/or any of its Representatives to Manufacture the Product in accordance with the Standard, in which event Vetter shall compensate Customer for any such costs and/or expenses up to an amount of [***] Euros per recall, subject to the Annual Cap; it being understood and agreed by and between the Parties that (i) in the event of gross negligence or willful misconduct, no limitations of Vetter's liability shall apply; and (ii) the provisions set forth in Section 14(1) shall apply to any recalled Product.

(5) Materials, Services. Notwithstanding anything to the contrary contained in this Agreement, and except as provided in Section 21(4), neither Vetter nor any of its Representatives shall be responsible or liable for any materials manufactured or supplied to the Facility by Customer or any third party (including Materials) or any testing or other services performed by any third party (other than the services in Section 23(8) referred to) if Vetter can prove that Vetter Pharma inspected, tested, used, stored and Manufactured in accordance with the Standard. Vetter shall transfer or cause to transfer to Customer any warranties as received in respect of either thereof, and Vetter shall reasonably assist Customer in pursuing any rights with respect to such warranties.

(6) Debarment. Each Party represents, warrants and covenants to the other Party that it and its Representatives shall not employ, contract with, or retain any person directly or indirectly to perform any Manufacturing or other obligations under this Agreement if (i) such person is presently debarred by the FDA pursuant to 21 U.S.C. 335a or its successor provisions, or the Party has knowledge that such a person is under investigation by the FDA for debarment; and/or (ii) such a person has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 CFR 12.70 or its successor provisions. In addition, each Party represents and warrants that it, and/or its Representatives, has nor or have not, as the case may be, engaged in any conduct or activity which could lead to any of the above-mentioned disqualification or debarment actions. If, during the Term, a Party or any Representative that has been employed or retained by such Party to perform, with respect to the Manufacturing or any other obligation under this Agreement, (x) comes under investigation by the FDA for a debarment action, disqualification or similar action; (y) is debarred or disqualified; or (z) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions, such Party shall without undue delay notify the other Party of such occurance.

(7) Corporate. Each of the Parties hereby represents and warrants to the other Party that (i) such Party is and shall remain duly organized, validly existing, and in good standing under the laws of the place of its establishment or incorporation; (ii) such Party has the full power, right and authority to execute and deliver this Agreement; (iii) the person(s) executing this Agreement is/are authorized to execute this Agreement; (iv) this Agreement is legal and valid and the obligations binding upon such Party are enforceable by their terms; (v) the execution, delivery and performance of this Agreement does neither conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; (vi) such Party shall not enter into any agreement, either written or oral, that would prevent it from fulfilling its responsibilities under this Agreement.

[***] 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.

(8) Representations. Vetter represents and warrants that (i) it shall use all commercially reasonable efforts to perform its obligations hereunder; (ii) it shall cause Vetter Pharma to assign professional personnel, qualified to perform the Manufacturing in a manner consistent with the Standard; (iii) it shall conduct the services in accordance with the Standard and generally accepted standards for the pharmaceutical industry in Germany, and the event of any conflicts between the foregoing requirements, the most stringent requirement shall be met so long as consistent with all Territory Laws; (iv) all Product that Vetter delivers to Customer pursuant to this Agreement shall, at the time of Delivery, not be adulterated or misbranded by Vetter and/or any of its Representatives within the meaning of the US Food, Drug and Cosmetics Act; (v) it and its Representatives shall not transfer to any third party any API or any Product, other than as required to fulfil its obligations under this Agreement as permitted by the terms of this Agreement; (vi) it shall cause Vetter Pharma to have obtained (or shall obtain prior to Manufacture of the Product or performance of other services hereunder), and shall remain in compliance with during the Term, all permits, licenses and other authorizations which are required under the Territory Laws for the Manufacturing of Product.

(9) Anti-Corruption. Customer is committed to observing applicable anti-corruption laws of the countries in which Customer and its affiliates operate, including the United States Foreign Corrupt Practices Act ("FCPA") and other Territory Laws dealing with bribery or corrupt practices. Customer requires its business associates to comply with Customer's ethical standards when dealing with third parties on behalf of Customer or in connection with an agreement with Customer and, therefore, Vetter understands and acknowledges that (i) it shall be prohibited in connection with services under this Agreement from providing or causing or permitting the provision of any bribe, kickback or other improper inducement to any Regulatory Authority or governmental officials; (ii) its obligation to comply with all applicable German anti-corruption laws; (iii) warrants that it shall comply with all applicable German anti-corruption laws in performing under this Agreement. Upon request, Vetter shall provide reasonable documentation related to compliance with Vetter's anti-corruption policies and shall complete Customer's anti-corruption questionnaire.

ARTICLE 21: LIMITATIONS

(1) Special Damages. Notwithstanding anything to the contrary contained in this Agreement, neither Party nor any of its Representatives shall be responsible or liable to the other Party and/or any of its Representatives for any reason whatsoever (even upon the occurrence of a tort with respect to the Product or otherwise) for loss of profits (except any profits contained in the prices to which Vetter may be entitled for completion of its contractual obligations), loss of good will, loss of business or special, incidental, indirect, exemplary or consequential damages, except any of the foregoing arises out of a breach of the provisions contained in the Confidentiality Agreement as modified by this Agreement.

(2) Representations. Except as in this Agreement expressly set forth, each Party agrees that neither the other Party nor any of its Representatives makes or has made any other representation, warranty, covenant or agreement (whether express or implied). Any representation, warranty, covenant or agreement set forth in this Agreement is exclusive and in lieu of any other warranties, written or oral, direct, implied or statutory, including, but not limited to, express or implied warranties for merchantability, quality or fitness for a particular purpose.

(3) Representatives. Notwithstanding anything to the contrary contained in this Agreement, it is expressly agreed by and between the Parties that no Representative of Vetter shall assume, to the extent permissible under the laws of Germany, any responsibility or liability, but Vetter shall be responsible and liable for the performance of any of its Representatives to the same extent as if Vetter had performed or failed to perform, all as contemplated or required hereunder, and any claim made under this Agreement (for clarity, specifically including the QA) shall exclusively, to the extent permissible under the laws of Germany, be made against Vetter.

(4) Exceptions. Nothing contained in this Agreement shall act to exclude or limit either Party's liability for (i) fraud; (ii) gross negligence and/or willful misconduct; and/or (iii) breach by it and/or its Representatives of confidentiality obligations to the other Party and/or its Representatives.

ARTICLE 22: TERM AND TERMINATION, SURVIVAL

(1) Term. This Agreement shall be in full force and effect as of the Effective Date. This Agreement, as may be amended or modified by and between the Parties in writing, shall continue to be in full force and effect until the Completion Date; provided, however, (i) any rights or obligations accrued prior to the Completion Date shall not prejudice or preclude any remedies either Party may have under this Agreement; (ii) this Agreement shall be in full force and effect, with respect to the Commercial Work, for an initial term of five (5) years. Upon the expiration of such initial term and any subsequent term, this Agreement shall automatically be renewed for subsequent terms of two (2) years each (any term collectively, the "Term") unless either Party shall notify the other Party twelve (12) months prior to the end of any term in writing of its intention to not renew this Agreement. For clarity, any rights or obligations accrued prior to the expiration of the Term or termination of this Agreement (respectively, the "Completion Date") shall not prejudice or preclude any remedies either Party may have under this Agreement.

(2) Termination for Breach. Each Party shall have the right to terminate this Agreement (with immediate effect or, if applicable, after the expiration of an applicable time period) upon prior written notice if the other Party is in major default in the fulfillment of any material obligation under this Agreement. The term "major default" shall include, but not be limited to (i) insolvency, bankruptcy, liquidation, or appointment of a receiver of any significant part of the property, of a Party and/or Vetter Pharma; (ii) in the case of any other default which can be cured, the failure to cure the default during a period of [***] after the giving of written notice specifying such default (unless it is evident that such default cannot be cured within ninety (90) calendar days), in which case the default shall upon notice be considered to be major; (iii) in respect of Customer, the failure to provide for or maintain product liability insurance as required under this Agreement, or pay any insurance premiums when due; and (iv) failure to establish mutual agreement with respect to a change required to satisfy Territory Laws in accordance with Section 18(4) within [***].

[***] 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.

(3) Special Termination. Customer shall have the right to terminate this Agreement with immediate effect upon receipt by Vetter of prior written notice if Customer determines in its sole reasonable discretion, upon completion of the Development Work only, that the Product cannot be commercialized, and/or if the commercialization of the Product must be suspended or terminated for medical, scientific, regulatory or technical reasons, subject to Section 8(2) or Section 15(2), and Section 22(4).

(4) Winding Down. Upon the Completion Date, Customer, in its sole discretion, shall either (i) pay any cancellation compensation for Product (for which Purchase Orders were issued) that Customer no longer wishes to purchase, unless termination was by Customer due to Vetter's uncured breach, in which case no such cancellation compensation shall be due; or (ii) shall purchase and Vetter shall sell to Customer, at the prices herein provided, any Product for which Purchase Orders have been or are required to be placed in accordance with the Development Schedule or any Commercial Forecast or Rolling Forecast given on or prior to the Completion Date and, at Vetter's prices thereof, all Sourced Materials and other materials ordered as contemplated in or permitted under this Agreement. Customer shall be responsible and liable to Vetter for any amounts accruing prior to the Completion Date including, but not limited to, amounts due under Section 8(2) for cancellation of the Development Work, and amounts due for Purchase Orders under Section 15(2) for Commercial Work; provided, however, it is agreed and understood by Vetter that any and all expenditures scheduled but not actually made due to such immediate termination shall be deducted from any of the foregoing amounts. Upon the Completion Date, Vetter shall arrange for delivery to Customer or destruction of any Customer Materials at the Facility, at the cost and/or expense of Customer. Upon the Completion Date, Vetter shall make available, as is and where is, to Customer the Equipment, if paid for by Customer. Vetter shall have returned to Customer all documentation (including copies thereof) constituting Information of Customer; provided, however, notwithstanding the foregoing, Vetter or any of its Affiliates may retain such limited quantity of the Product, the Customer Materials (all thereof sufficient for two (2) analyses) and such documentation as may be necessary for proper record keeping in satisfaction of Territory Laws. Upon the Completion Date, Customer shall return to Vetter any and all documentation (including copies thereof) provided to Customer and constituting Information of Vetter and/or any of its Affiliates; provided, however, Customer may retain such limited number thereof as may be necessary for proper record keeping in satisfaction of Territory Laws.

(5) Survival. Articles 19 (Intellectual Property), 20 (Liability, Indemnification and Insurance), 21 (Limitations) as well as Sections 22(4) (Consequences), 23(2) (Confidentiality) as therein set forth, 23(3) (United Nations), 23(10) (Interpretation), 23(13) (Dispute) and this Section 22(5) shall survive the Completion Date.

ARTICLE 23: MISCELLANEOUS

(1) Force Majeure. No Party shall be responsible or liable to the other Party and/or any of its Representatives, and no default shall be deemed to have occurred, for failure or delay in performing any obligations or for other non-performance if such failure, delay or other non-performance is caused by or arises from any strike, stoppage of labor, lockout or any other labor trouble, shortage of energy or raw material or any inability to obtain any materials or shipping space, breakdown or delays of carriers or shippers, default or delay by any supplier or sub-contractor or other events due to internalization of operations and services typically and customarily provided by a third party, fire, flood, lightning, fog, storm, unusual weather conditions, explosion, accident, earthquake, volcanic ash, epidemics, act of God, any public enemy, sabotage, invasion, war (declared or undeclared), riot, embargo, governmental or administrative act or restraint, prohibition on import or export of the Product or materials incorporated therein or parts thereof, or any matter or cause that is unavoidable by or beyond the reasonable control of the affected Party (each, an event of "Force Majeure"). A Party shall be under no obligation to settle a strike, labor stoppage, lockout, or any other labor trouble by entering into any agreement to settle any thereof and until any such matter is settled to the satisfaction of the affected Party, such matter shall continue to be deemed Force Majeure. Any and all of the foregoing shall also apply to a Party to the extent that an Affiliate of such Party is performing or providing any service (including under Section 23(8) referred to) or work in connection with the obligations of a Party. A Party claiming Force Majeure shall promptly notify the other Party specifying the cause and probable duration of the failure, delay or other non-performance. Neither Vetter nor any of its Representatives shall be under any obligation to fulfill any Purchase Order which has been, or should have been scheduled to be performed during a time period of Force Majeure; provided, however, a Party so affected shall undertake every commercially reasonable effort to fulfill its contractual obligations to the extent reasonably possible under the circumstances. If Vetter experiences a Force Majeure event that interferes with Manufacturing of the Product at the Facility, Vetter shall, at Customer's discretion and request, cooperate in good faith with Customer in expeditiously transferring Manufacturing to another of Vetter Pharma's facilities, if available. The Parties shall mutually discuss and implement in good faith an agreed-upon action plan for such transfer. If it is evident that the Force Majeure event will last longer than [***] and Vetter is not able to accommodate such a transfer in a timely fashion, Customer shall have the right to cancel any and all affected Purchase Orders without penalty.

(2) Confidentiality. The provisions of the Confidentiality Agreement shall govern this Agreement in every respect (and the term Purpose as therein defined shall be deemed to include the matters set forth or contemplated in this Agreement), except that the confidentiality obligations in the Confidentiality Agreement contained shall survive the Completion Date and shall remain in full force and effect for a period of ten (10) years from the Completion Date. Each Party agrees to indemnify, defend and hold the other Party and/or any of its Representatives harmless from and against any and all Costs resulting from or arising out of breach by it and/or any of its Representatives or its Affiliates or its Affiliates' Representatives of the provisions of this Section or the Confidentiality Agreement. In addition to other permitted disclosures set forth in the Confidentiality Agreement, Customer shall be permitted to disclose Vetter's Confidential Information in submissions to Regulatory Authorities in connection with the Product and its Manufacture. The terms of this Agreement shall be considered as each Party's Confidential Information; provided, however, that each Party shall be permitted to disclose (i) the Quality Agreement and submit the Quality Agreement to any Regulatory Authority or other regulatory or governmental agency, including the FDA; (ii) this Agreement (redacted by Customer as it determines, in its sole discretion, to be permitted and appropriate based on the advise of its counsel, and after having provided Vetter a copy of such redactions and opportunity to comment thereon, which comments shall be considered by Customer in good faith) to the US Securities and Exchange Commission, the US Federal Trade Commission and/or the US Department of Justice as may be required by the Territory Laws or other applicable law or regulation.

[***] 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.

(3) United Nations. The United Nations Convention on Contracts for the International Sale of Goods shall have no application to, and shall be of no force and effect with respect to, the matters set forth or contemplated in this Agreement.

(4) Entire Agreement. This Agreement constitutes the entire agreement with respect to the matters set forth or contemplated in this Agreement and supersedes in any and all respects any prior communication, proposal, quotation, negotiation, conversation, discussion and agreement concerning the matters set forth or contemplated in this Agreement, and any terms and conditions thereof shall be null and void.

(5) Conflict. In the event of any conflict between any provision of the Quality Agreement and the other provisions of this Agreement, the provisions of this Agreement shall exclusively govern and control, except for any quality related matters of the Manufacture of Product used for development, which shall be governed by the DQA and, for clarity, in the event of any conflict between the terms of the CQA and the other provisions of this Agreement, the provisions of this Agreement shall control, except for any quality related matters of the Manufacture of Products intended by Customer for commercial use, which shall be governed by the CQA; provided, however, that, with respect to all of the above, the terms of this Agreemet shall control in all matters concerning defective Product. Notwithstanding anything set forth herein above, nothing in the Quality Agreement shall act or be deemed to amend the terms of this Agreement.

(6) Severability. Any provision of this Agreement held void, invalid or unenforceable shall be replaced by a mutually agreed provision that is effective, valid and enforceable and in compliance with the lawful purposes and intentions as contained in or determinable under this Agreement. Any matter not initially considered shall be resolved by incorporating such reasonable provision in order to complete this Agreement which approaches to the maximum extent such lawful purposes and intentions. The effectiveness, validity and enforceability of this Agreement shall remain independent of any provision which might be or has become void, invalid or unenforceable except if any replacement thereof is not possible and this Agreement would then not have been entered into.

(7) Amendments. Any amendment or modification of the provisions in this Agreement contained, specifically including this Section, shall take effect only by a written document signed and duly executed. The Appendices may be amended from time to time separately and independently of the Quality Agreement.

(8) Assignment. Neither this Agreement nor any right or obligation of each Party shall be assignable or transferable, except as herein provided, without the prior written consent of the other Party; provided, however, Vetter may cause internal logistic and warehousing operations to be performed by an independent subcontractor (currently Grieshaber Logistik GmbH, 88250 Weingarten, Germany ("Grieshaber")) and Vetter shall be and remain responsible and liable for any performance of or failure to perform by such contractor; and (ii) Customer may assign this Agreement to a successor-in-interest by virtue of merger or acquisition or sale of its relevant business assets; provided, however, Vetter's prior written consent shall be required if (i) the assignee of this Agreement or acquirer of Customer (herein collectively, "Assignee") disagrees with assuming the performance of Customer's rights and obligations under this Agreement as herein set forth; (ii) Customer does not provide prompt written notice to Vetter following any such assignment; (iii) any Assignee should be a third party that earns more than five percent (5%) of its revenues in the full fiscal year prior to the assignment from the sale of biosimilars or performance of contract manufacturing for the filling of sterile vials; (iv) any Assignee should not have the technical capabilities, expertise and the financial capacity (in each case at least commensurate with that of Customer) to perform the obligations to be assumed by such Assignee under this Agreement and/or the Quality Agreement); it being agreed and understood that Customer shall not be released of its obligations of confidentiality under Section 23(2) and, for clarity, such Assignee shall assume such confidentiality obligations thereunder in addition to Customer, and that Customer shall be responsible for paying the Transition Compensation within [***] of receipt of an undisputed invoice therefore (for clarity, Customer shall not be responsible for payment of amounts an Assignee would owe as a result of changes requested by such Assignee to the development schedule or other changes to this Agreement or the Quality Agreement).

[***] 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.

(9) Legal Notices. Any and all legal notices, requests, demands and other communication hereunder shall be in English (and any and all costs and/or expenses associated with necessary translation shall be borne by the incurring Party), be addressed as follows, or to such other address or fax number as each Party may specify in a notice pursuant to this Section, and be deemed duly given upon receipt if and when such receipt is on a Business Day and during normal business hours of the recipient or otherwise on the then-succeeding Business Day, and if mailed by registered or certified mail, return receipt requested, or by signed fax together with the respective transmission report (and for greater certainty, be deemed unduly given if delivered by email):

If to Customer: Omeros Corporation
Attn. General Counsel
201 Elliott Avenue West, Seattle, Washington 98119, United States
Fax: +1 (206) 676-5005

If to Vetter: Vetter Pharma International GmbH
Attn. Managing Director
Eywiesenstraße 5, 88212 Ravensburg, Germany
Fax: +49 (751) 3700-4200

With copy to: Vetter Pharma-Fertigung GmbH & Co. KG
Attn. Head of Legal Department
Schützenstraße 87, 88212 Ravensburg, Germany
Fax: +49 (751) 3700-6070

(10) Interpretation. The headlines of the Articles and the Sections are for convenience of reference only and shall not affect the interpretation of this Agreement. Any understanding or interpretation of any legal term contained or referred to in this Agreement shall solely be defined and interpreted in accordance with the laws of Switzerland, irrespective of any other meanings or interpretations under any other source or body of law as may be found applicable to this Agreement by any court that may claim or assess jurisdiction under any conflict-of-laws provisions or otherwise, any of which other meanings or interpretations shall have no application to and be of no force and effect with respect to the matters herein set forth, referred to or contemplated.

(11) Independent Parties. Each Party and any of its Affiliates are independent parties and nothing in this Agreement is intended or shall be deemed to create a partnership, a joint venture or a relationship of an agent with its client or an employer with its employee. No Party or any of its Affiliates shall have authority to make any statements, press releases, representations or commitments of any kind, or take any action which shall be binding on the other Party and/or any of its Affiliates, except as may be expressly authorized in writing which authorization shall not be unreasonably withheld.

(12) Timely Performance. Any failure by either Party to request performance or non-performance by the other Party and/or any of its Affiliates or to claim a breach of this Agreement shall neither be construed as a waiver of any right under this Agreement nor affect any subsequent failure to request performance or non-performance or claim a breach, nor affect the effectiveness, validity and enforceability of this Agreement or any part thereof nor prejudice or preclude such Party with respect to any subsequent action. Any request for performance or non-performance by either Party and/or any of its Affiliates or claim of a breach of this Agreement, including breach of this Section, shall be effective, valid and enforceable only if such request or claim is reduced to writing.

(13) Dispute. (a) Internal Resolution. The Parties shall attempt to amicably settle and in good faith resolve any controversy, claim or dispute in connection with this Agreement, by negotiations between designated representatives prior to resorting to any court action or arbitration action permitted by and subject to Section 13(b). If no amicable settlement and good faith resolution thereof has been achieve within [***], such controversy, claim or dispute may be brought by written notice to the executive management representatives who shall use reasonable endeavors to amicably settle and in good faith resolve such controversy, claim or dispute [***] of receipt of said notice. If no amicable settlement and good faith resolution thereof has been achieved within said further time period, such controversy, claim or dispute shall be brought by written notice to the highest management representatives who shall use reasonable endeavors to amicably settle and in good faith resolve such controversy, claim or dispute within further [***] of receipt of said further notice.

(b) Arbitral Resolution. With respect to any controversy, claim or dispute arising under this Agreement not settled amicably by and between the Parties, either Party may, at its sole discretion, refer such controversy, claim or dispute to arbitration under the Rules of Arbitration of the International Chamber of Commerce ("AICC Rules" which shall, in addition to the substantial/material laws of Switzerland, be the sole and exclusive rules and procedures for the resolution of any such controversy, claim or dispute, and any and all applicable statutes of limitation shall be tolled while the procedures specified or referred to herein are pending), to be finally settled by three (3) arbitrators, appointed in accordance with the AICC Rules and only applying the substantial/material laws of Switzerland. The seat of arbitration shall be Zurich, Switzerland. The language to be used in the arbitral proceedings shall be English. Annexes to any procedural document may also be provided in the German language. The arbitral tribunal shall have the authority to order production of documents only in accordance and within the limits of the IBA Rules on the Taking of Evidence in International Arbitration as current on the Effective Date or thereafter at the relevant point in time. Any decision or arbitral award delivered in the arbitration shall be reasoned and in writing, and shall be final and binding on each of the Parties and enforceable in any competent Swiss court of law. The arbitrators shall have no power or authority to award damages waived under any limitation of liabilities provision herein. The arbitrators shall not act as amiable compositeur. The Parties each undertake to comply with any award without delay and shall be deemed to have waived their respective right to any form of recourse insofar as such waiver can validly be made. The existence and content of the arbitral proceedings and any rulings or award shall be kept confidential by each of the Parties and members of the arbitral tribunal except to the extent that disclosure may be required of a Party to fulfill a legal duty, protect or pursue a legal right, or enforce an award before a Swiss state/ordinary court or other judicial Swiss authority. Notwithstanding anything in the foregoing to the contrary, before making such information public, the interested Party shall notify the other Party, in writing, and shall afford the other Party a reasonable opportunity to protect its interests if the other Party deems it necessary. All monetary awards shall be stated and payable in Euros. Each of the Parties irrevocably waives its right to a trial by jury, if any, and agrees that all prior negotiations and proceedings relating to such claims as provided herein shall be deemed inadmissible compromise negotiations. If either Party seeks to initiate a legal action or proceeding inconsistent with these provisions, the other Party shall be entitled to recover all costs and expenses, including reasonable attorneys' fees and any court fees, incurred in defense of such action or proceedings; provided, however, nothing in this Section shall preclude any Party from filing a complaint and seeking interim or other provisional relief from a Swiss court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a controversy, claim or dispute, either prior to or during any arbitration if, in its sole judgment, necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding, in aid of arbitration, and despite such action, each of the Parties shall continue to participate in good faith in the procedures specified herein.

(c) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with and governed by the laws of Switzerland, regardless of the laws which might govern under any conflict-of-law principles.

(Page remainder left blank intentionally, immediately followed by two (2) signatures pages.)

[***] 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.

IN WITNESS WHEREOF, duly authorized representatives of Customer have semi-executed this Agreement for counter-execution by Vetter (and by Vetter Pharma, subject to the below provision), respectively on the days and year at the places below written.

OMEROS CORPORATION

Seattle, Washington, dated this 9th day of May (month), 2019

(signed) /s/ Gregory A. Demopulos

Name: Gregory A. Demopulos, M.D.

Title: Chairman & CEO

(signed) /s/ Marcia S. Kelbon

Name: Marcia S. Kelbon

Title: VP, Patents and General Counsel

VETTER PHARMA INTERNATIONAL GMBH

Ravensburg, Germany, dated this 10th day of May (month), 2019

(signed) /s/ Christine Fürst

Name: Christine Fürst

Title: Senior Director Key Account Management Europe

(signed) /s/ Jeffrey C. Ellenburg

Name: Jeffrey C. Ellenburg

Title: Director Key Account Management Europe

(Page remainder left blank intentionally, immediately followed by the second signatures page.)

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned hereby unconditionally and irrevocably, merely as surety and not as primary obligor, guarantees to Customer, for the benefit of Customer, the full and prompt payment and performance, when due and at all times thereafter until made, of all obligations (monetary or otherwise) of Vetter under this Agreement (including as it may be amended from time to time). Vetter Pharma acknowledges and agrees that Vetter and Customer may amend, modify or expand this Agreement without providing notice thereof to Vetter Pharma or obtaining Vetter Pharma's consent and the obligations and liabilities of Vetter Pharma under this guaranty shall not be released or otherwise affected or impaired as a result thereof. Vetter Pharma represents and warrants to Customer that it controls (such term as used in Section 1(2) of this Agreement) Vetter.

VETTER PHARMA-FERTIGUNG GMBH & CO. KG

Ravensburg, Germany, dated this 10th day of May (month), 2019

(signed) /s/ Christine Fürst	(signed) /s/ Jeffrey C. Ellenburg
Name: Christine Fürst	Name: Jeffrey C. Ellenburg
Title: Senior Director Key Account Management Europe	Title: Director Key Account Management Europe

Annexes Omitted from Combined Development and Commercial Supply Agreement

The following annexes have been omitted pursuant to Item 601(a)(5) of Regulation S-K. Omeros agrees to furnish a copy of such omitted exhibits to the Securities and Exchange Commission or its staff upon request.

Annex 1 – Development Schedule
Annex 2 – Prices
Annex 3 – Equipment
Annex 5 – Quality Agreement

ANNEX 4: COMMERCIAL PRODUCT SUPPLY CHAIN TERMS

This Annex provides herein below the commercial Product supply chain terms that are applicable to the supply of no more than [***] batches of Product per [***] ("Low Volume Manufacturing Phase") as defined in Section 3 of this Annex 4 below, as well as to the supply of more than [***] batches per [***] ("Standard Manufacturing Phase", the further details of which shall mutually be inserted by the Parties below, by means of an amendment hereof), all negotiated in good faith and mutually agreed in this Annex 4 prior to commencement of each such phase, it being specifically agreed and understood by Customer that at such point in time referred to in the final sentence of Section 3 of this Annex 4 with no such amendment in place, no Production can occur, and that the negotiation and planning of the Standard Manufacturing Phase will most likely require a period of at least [***], as respectively mentioned below with respect to the Launch Batch.

1.	PURPOSE	With this Annex 4, Customer and Vetter intend to cover the commercial production, by implementing the following terms. Customer expects a low Manufacturing volume during the first years after launch of commercial sales of Product (the forecasting of the Launch Batch being the "Launch"). To simplify the process at Vetter and at Customer, the following terms were split into two parts: - Low Volume Manufacturing phase (Section 3, detailed below) - Standard Manufacturing Phase (Section 4, detailed below)

[***] 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.

2.	LONG RANGE FORECAST	The Long Range Forecast shall be provided by Customer to Vetter [***] prior to the first delivery of a batch manufactured as part of the Commercial Work ("Launch Batch"). This is considered as the first "Commercial Forecast". Customer shall provide a good faith estimate of the total annual volumes anticipated for a ten (10) years' rolling period (the "Long Range Forecast"), or such shorter period remaining for the Term of this Agreement, of: Vials visually inspected by Vetter Pharma ([***]) After first provided by Customer, the Long Range Forecast shall be sent to Vetter once a year, by August 7th of each year. The Long Range Forecast is non-binding and only for planning purposes, except for the determination of the end of the Low Volume Manufacturing Phase as set forth in Section 3 hereof below. Significant forecast changes shall be indicated to Vetter reasonably promptly after they are known to Customer, and need to mutually be discussed.
3.	LOW VOLUME MANUFACTURING PHASE	The Low Volume Manufacturing Phase is defined as the time during which Customer may order, and Vetter shall have Manufactured a maximum of [***] batches per [***], and a maximum of such amount of batches per calendar quarter as separately agreed with Vetter Pharma. The Low Volume Manufacturing Phase ends at the point in time within a Long Range Forecast when, for the first time, more than [***] have been forecasted by Customer (i.e., the date when the [***] batch is forecasted to be Manufactured), in the Long Range Forecast, of the next calendar year provided on August 7th of each year

[***] 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.

4.	PURCHASE ORDERS	(1) Purchase Orders: For the Launch Batch (first batch), the Purchase Order shall be issued at least [***] before the expected Delivery Date. All other Purchase Orders shall be provided by the latest on the [***] during the Term, on a recurring monthly basis, for the then-following [***] (the "Rolling Forecast"), but at least [***] before the expected Delivery Date, except as may otherwise may be accepted at the discretion of Vetter. In the event that a Purchase Order should be less than the previously forecasted requirements for the Product set forth in the Rolling Forecast, Customer shall pay to Vetter the price therefore as set forth under this Agreement except if (i) otherwise agreed with Vetter; or (ii) Vetter is able to book alternate product into any modified or cancelled slot without financial loss to Vetter, all as in this Annex 4 set forth and subject thereto. (2) Volumes: Order quantity according to Purchase Order, at least: Commercial batch: [***]/batch to [***]/batch (3) Rescheduling of Batches: Flexibility for rescheduling batches without charge: For the first year after the Launch, a one-time flexibility, or more often as may be permitted at the discretion of Vetter, to postpone for a maximum of [***], for the second year after the Launch, for a maximum of [***] and, for commercial Manufacture, in the third and in each of the then-following years during the Low Volume Manufacturing phase, for a maximum of [***], as long as shifted within the first [***] after Purchase Order issued by Customer is accepted by Vetter (See Attachment 1 hereof). For sake of clarity: Might be pushed one time, by a maximum of [***] (for the first year after the Launch). All changes to any Delivery Date, after the initial Purchase Order has been issued, are subject to confirmation by Vetter and availability in the production schedule of Vetter Pharma. (4) Cancelling of Batches: Compensation for cancelled batches: In case of cancellation of a Purchase Order for a batch for which a Purchase Order has been issued and accepted, in the first two (2) years after the Launch, the following compensation due for payment by Customer to Vetter shall apply: ● Compensation = [***] percent ([***]%) of the then-valid purchase price of the cancelled yet previously ordered batch; provided, however, that: (i) if a batch was previously postponed from initial Purchase Order date with less than [***] notice, or is currently being Manufactured; or (ii) the Manufacture is planned to occur in the then-next [***], then, in either of the foregoing cases, compensation for payment to Vetter by Customer, in the amount of one hundred percent (100%) of the then-valid batch purchase price of the cancelled ordered batch, shall apply and be due. Notwithstanding the above, to any extent that Vetter is able to use, for another third party customer, a slot (or part thereof) originally dedicated to Manufacture for Customer that is then released by Customer due to decreasing its forecasted demand, Vetter shall not require, to that pro-rated extent, Customer to pay for any such released capacity (or part thereof) and shall refund to Customer any advanced payments made by Customer for such slot. In case of cancellation of a Purchase Order for a batch for which a Purchase Order has been issued and accepted for the commercial Manufacture in the third and subsequent years during the Low Volume Manufacturing Phase, the following compensation due for payment by Customer to Vetter shall apply: ● Compensation ([***] prior to the scheduled Manufacture date) = [***] percent ([***]%) of the then-valid purchase price of the cancelled ordered batch ● Compensation ([***] prior to scheduled Manufacture date) = [***] percent ([***]%) of the then-valid purchase price of the cancelled ordered batch ● Compensation ([***] prior to scheduled Manufacture date) = [***] for the cancelled ordered batch; provided, however, if a batch was already postponed from the initial Purchase Order date, with less than [***] prior notice, or is currently being Manufactured, or the Manufacturing is planned in the then-next [***], compensation by [***] percent ([***]%) of the then-valid purchase price of the cancelled ordered batch shall apply. Notwithstanding the above, to any extent that Vetter is able to use for its own purposes or for a third party a slot (or part thereof) originally dedicated to Manufacture for Customer that is then-released by Customer due to decreasing its forecasted demand, Vetter shall not require Customer to pay for any such released capacity (or part thereof). For sake of clarity: In case of a one-time postponement of the Purchase Orders (for Vetter, like a full (100%) reduction in this month) during the third and subsequent years, further reductions or postponements of these still postponed volumes/Purchase Orders during the same twelve (12)-months' period, are not possible (Customer's obligation shall then be a full (100%) commitment for number of batches, at the then-valid batch purchase price).

5.1.	FREEDOM OF FILLING DAY	Customer orders and forecasts shall be based on the requested delivery month or requested Delivery Date. Vetter confirms and invoices against the actual Delivery Date. There is no obligation of Vetter to provide an exact filling day with the forecast or any order tracking tool. Vetter has the flexibility in filling days. Vetter shall always try to prioritize orders with critical shelf life. On the basis of the Rolling Forecast provided by Customer, Vetter shall calculate an ideal filling date. The ideal filling date can be advanced or delayed (to build manufacturing campaigns), by a maximum of [***] without agreement by Customer, subject to Customer Materials' availability at Vetter Pharma. In case of a mutually agreed significant increase of demand in the Long Range Forecast, Vetter and Customer agree that campaign building is possible in general. Additional equipment shall be sourced and invoiced separately to Customer. Vetter shall have the freedom on campaign building.
5.2.	PIECES PER BATCH	The commercial batch size is defined as between [***] and [***] units. Vetter holds the right to periodically adjust prices within the parameters set forth in this Agreement. As there is no historical experience available for the Product, there shall be a good faith discussion once a year with the discussion of the annual Rolling Forecast in August, of unit pricing, storage pricing, etc., with the maximum for any agreed pricing changes to be consistent with the terms of the Agreement.
5.3.	PURCHASE ORDER CONFIRMATION/ GOOD DELIVERY	Vetter shall send the Purchase Order confirmation in the first week of the month following the month of Purchase Order receipt, due to the internal planning cycle which takes place in week No. 2 and No. 3 of each month, with a plausibility check in week No. 4. Vetter and Customer shall create a set of manufacturing KPIs, tracking the ordering process for quantity and delivery time fulfillment during the launch period. Those KPIs shall mutually be tracked and presented during an annual business review meeting. If irregularities or challenges should be identified, actions shall be mutually defined during the business review meetings.

[***] 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.

5.4.	ARRIVAL OF API/ EXCIPIENTS/ MATERIAL/ DOCUMENTS	Vetter shall call-off (i.e., request) the API for confirmed Purchase Orders from Customer, [***] before the requirement of being present at the Facility, but at the earliest when the Purchase Order is provided by Customer. Customer shall send a confirmation for the delivery of the API ("API Delivery Date") within [***] following Vetter's acceptance of a Purchase Order, upon which Vetter can rely on. The API shall be released for Manufacturing at Vetter Pharma, at a minimum of [***] prior to the fill date. As of the Effective Date, the API shall be delivered by Customer, and side samples shall be provided. The API should be delivered as required on the order from Vetter or Vetter Pharma, as mentioned above, but at a minimum of [***] prior to the planned filling date unless otherwise agreed by Vetter Pharma. Receipt of materials may be rejected by Vetter Pharma if not delivered in accordance with this Agreement (including, for clarity, the Quality Agreement, or as otherwise reasonably agreed without violation of cGMP). If this results in the loss of a filling slot that is not utilized for another third party customer of Vetter, it shall be considered as a cancellation and treated with possible compensation.
5.5.	MATERIALS SOURCING	The target is to implement a second source for critical secondary packaging materials (excluding device materials and container closure components) to increase supply security. If no second source is implemented, a higher safety stock level must be agreed to assure a reliable delivery. Vetter and Customer shall work together in good faith to resolve any sourcing issues for device materials and container closure components.
5.6.	MATERIAL INVENTORY LIST	Sourced Materials shall be ordered in volumes based on the provided Purchase Orders and Rolling Forecasts, as well as the specified safety stocks, such volumes to include the required minimum quantities which have to be purchased depending on the supplier. If demand is dropping significantly or a change of the Agreed Process Specifications is performed, Customer shall pay compensation to Vetter for the cost of destroying obsolete materials.
5.7.	SAFETY STOCK	In addition to the regular stock, in volumes related to Purchase Orders, Vetter shall cause Vetter Pharma to source and keep [***] of the Sourced Materials required for Manufacture of the annual Rolling Forecast volume, as safety stock but, at minimum, the amount covering [***]. Additional safety stock can be mutually agreed upon and shall separately be quoted and invoiced to Customer.

[***] 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.

5.8.	PICK-UP OF FINISHED GOODS	After Vetter Pharma's release of the Product, Customer shall (or its forwarder may) contact Transporeon directly in order to get access to the system, to reserve a pick-up slot at Vetter Pharma. The delivery is [***], with a standard on-time pick-up on the Delivery Date. Vetter grants Customer four (4) weeks of free storage after the confirmed Delivery Date or Vetter Pharma's batch release (latest date counts). A pick-up of such stored Products after this period shall be invoiced by Vetter, with compensation for such storage then-due for payment by Customer, of [***] Euros ([***]€) per pallet per [***].
5.9.	INVOICING/ PAYMENT TERMS	Invoices shall be sent by Vetter to Customer after the completion of the activities (which, for batch Manufacture, shall occur when the Product has been released by Vetter Pharma, for pick-up at the Facility by Customer) with [***] net payment term, subject to and as further defined in this Agreement above.
5.10.	LOGISTIC SERVICES	The following additional logistic services can be offered from Vetter: - [***] - Specific sample shipping services. Those services shall be quoted and agreed upon separately. For the sake of clarity, in the case that API shall be received by Vetter Pharma arriving from outside of the EU, by a third party CDS manufacturer or by Customer, and such API import shall, upon request from Customer, be handled by Vetter Pharma, then Customer shall inform Vetter in advance [***] and the following issues shall be clarified. ► Impact issues Section 72a German Medicines Law (AMG) declaration ► Tax/Customs impact ► API value Reimbursement of tax advance impact: [***] percent ([***]%) annual interest on VAT financing.

[***] 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.

5.11.	CUSTOMS/ IMPORT/ EXPORT	Vetter's Logistic Service Center shall be notified at least two (2) days in advance of any arrival of goods. For tri-angular arrangements, the customs' invoice shall be provided at least two (2) days in advance. If Vetter Pharma should import the API, the actual value of the API must be stated on the import documents, by German law. Vetter cannot provide any assistance without such information.
5.12.	KPIs	To jointly work on improvements of the processes, Vetter can offer certain key performance indicators ("KPIs"). Those KPIs shall be mutually agreed on to be presented and discussed with Customer within an annual business review meeting.
5.13.	JAPAN QUALITY	The supply of Japanese Quality is currently not within the scope of the project and not targeted to be implement at Vetter Pharma, for this Product; provided, however, Vetter is open to offer an evaluation of this service if requested by Customer. During the implementation of a Japanese quality at Vetter and the Facility, this Annex 4 needs to be reviewed and, if needed, adapted, before the planned revision cycle.
6.	REVISION	Sections 1 through 6 of this Annex 4 shall be mutually discussed and may, based on mutual written agreement of authorized officials of each Party only, be revised during a business review meeting targeted to occur at the latest after completing the 2rd year of commercial Manufacture.

ATTACHMENT 1 OF ANNEX 4: ILLUSTRATION

For illustrative purposes only:

[***]

[***] 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.

Exhibit 19.1

OMEROS CORPORATION

_____

INSIDER TRADING POLICY

_____

Adopted June 26, 2023

TABLE OF CONTENTS

TABLE OF CONTENTS
(Continued)

INTRODUCTION

Omeros Corporation (together with its subsidiaries, the "***Company***") opposes the unauthorized disclosure of any nonpublic information acquired in the course of your service with the Company and the misuse of material nonpublic information in securities trading. Any such actions will be deemed violations of this Insider Trading Policy (the "***Policy***").

Legal prohibitions on insider trading

The antifraud provisions of U.S. federal securities laws prohibit directors (Board members), officers, employees and other individuals who possess material nonpublic information from trading on the basis of that information. Transactions will be considered "on the basis of" material nonpublic information if the person engaged in the transaction was aware of the material nonpublic information at the time of the transaction. It is not a defense that the person would have entered into the transaction even if he or she did not know the information.

Disclosing material nonpublic information directly or indirectly to others who then trade on that information or who make recommendations or express opinions as to transactions in securities while aware of material nonpublic information (which is sometimes referred to as "***tipping***") is also illegal. Both the person who provides the information, recommendation or opinion and the person who trades based on it may be liable.

These illegal activities are commonly referred to as "***insider trading***." State securities laws and securities laws of other jurisdictions also impose restrictions on insider trading.

In addition, a company, as well as individual Board members, officers and other supervisory personnel, may be subject to liability as "controlling persons" for failure to take appropriate steps to prevent insider trading by those under their supervision, influence or control.

Detection and prosecution of insider trading

The U.S. Securities and Exchange Commission (the "***SEC***"), the Financial Industry Regulatory Authority (FINRA) and The Nasdaq Stock Market use sophisticated electronic surveillance techniques to investigate and detect insider trading, and the SEC and the U.S. Department of Justice pursue insider trading violations vigorously. Cases involving trading through foreign accounts, trading by family members and friends and trading involving only a small number of shares have been successfully prosecuted.

Penalties for violation of insider trading laws and this Policy

Civil and criminal penalties. As of the effective date of this Policy, potential penalties for insider trading violations under U.S. federal securities laws include:

- damages in a private lawsuit;
- disgorging any profits made or losses avoided;
- imprisonment for up to 20 years;
- criminal fines of up to $5 million for individuals and $25 million for entities;
- civil fines of up to three times the profit gained or loss avoided;
- a bar against serving as an officer or director of a public company; and
- an injunction against future violations.

Civil and criminal penalties also apply to tipping. The SEC has imposed large penalties in tipping cases even when the disclosing person did not trade or gain any benefit from another person's trading.

Controlling person liability. As of the effective date of this Policy, the penalty for "controlling person" liability is a civil fine of up to the greater of $2.479 million or three times the profit gained or loss avoided as a result of the insider trading violations, as well as potential criminal fines and imprisonment.

Company disciplinary actions. If the Company has a reasonable basis to conclude that you have failed to comply with this Policy, you may be subject to disciplinary action by the Company, up to and including dismissal for cause, regardless of whether your failure to comply with this Policy results in a violation of law. It is not necessary for the Company to wait for the filing or conclusion of any civil or criminal action against an alleged violator before taking disciplinary action. In addition, the Company may give stop transfer and other instructions to the Company's transfer agent to enforce compliance with this Policy.

Compliance Officers

Please direct any questions, requests or reports as to any of the matters discussed in this Policy to the Company's General Counsel or another attorney in the Company's Legal Department designated by the General Counsel (the "***Compliance Officers***"). The Compliance Officers are generally responsible for the administration of this Policy. The Compliance Officers may select others to assist with the execution of their duties (including pre-clearance of trades).

Reporting violations

It is your responsibility to help enforce this Policy. You should be alert to possible violations and promptly report violations or suspected violations of this Policy to a Compliance Officer. If your situation requires that your identity be kept secret, your anonymity will be preserved to the greatest extent reasonably possible. If you wish to remain anonymous, send a letter addressed to both of the Compliance Officers at the Company's principal executive offices. If you make an anonymous report, please provide as much detail as possible, including any evidence that you believe may be relevant to the issue. While we will attempt to accommodate your desire to remain anonymous, we may need to know and disclose your identity to conduct an investigation and, if any is required, to take remedial action.

Personal responsibility

The ultimate responsibility for complying with this Policy and applicable laws and regulations rests with you. You should use your best judgment at all times and consult with your legal and financial advisors, as needed. We advise you to seek assistance if you have any questions at all regarding insider trading. The rules relating to insider trading can be complex, and a violation of insider trading laws can carry severe consequences.

PERSONS AND TRANSACTIONS COVERED BY THIS POLICY

Persons covered by this Policy

This Policy applies to all Board members, officers and employees of the Company as well as other individuals that the Company may designate as being subject to this Policy by written notice from a Compliance Officer to such individual (each a "***designated person***"). The Company may also determine that other persons should be subject to this Policy, such as contractors or consultants who have access to material nonpublic information. References in this Policy to "you" (as well as general references to Board members, officers, employees, contractors and consultants of the Company and designated persons) should also be understood to include members of your immediate family, persons with whom you share a household, persons that are your economic dependents and any other individuals or entities whose transactions in securities you influence, direct or control. You are responsible for making sure that these other individuals and entities comply with this Policy.

Types of transactions covered by this Policy

Except as discussed in the section entitled "**Limited Exceptions**," this Policy applies to *all* transactions *involving* the securities of the Company or the securities of other companies as to which you possess material nonpublic information obtained in the course of your service with the Company. This Policy therefore applies to purchases, sales and other transfers of common stock, options, warrants, preferred stock, debt securities (such as debentures, bonds and notes) and other securities. This Policy also applies to any arrangements that affect economic exposure to changes in the prices of these securities. These arrangements may include, among other things, transactions in derivative securities (such as exchange-traded put or call options), hedging transactions, short sales and certain decisions with respect to participation in benefit plans. This Policy also applies to any offers with respect to the transactions discussed above. You should note that there are no exceptions from insider trading laws or this Policy based on the size of the transaction.

Responsibilities regarding the nonpublic information of other companies

This Policy prohibits the unauthorized disclosure or other misuse of any nonpublic information of other companies when that information is obtained in the course of employment with, or other services performed on behalf of, the Company, such as the Company's distributors, vendors, customers, collaborators, suppliers and competitors. This Policy also prohibits insider trading and tipping based on the material nonpublic information of such other companies.

Applicability of this Policy after your departure

You are expected to comply with this Policy until such time as you are no longer affiliated with the Company *and* you no longer possess any material nonpublic information subject to this Policy. In addition, if you are subject to a trading blackout under this Policy at the time you cease to be affiliated with the Company, you are expected to abide by the relevant blackout period and any other trading restrictions imposed by applicable law and regulation.

No exceptions based on personal circumstances

There may be instances where you suffer financial harm or other hardship or are otherwise required to forego a planned transaction because of the restrictions imposed by this Policy. Personal financial emergency or other personal circumstances are not mitigating factors under securities laws and will not excuse a failure to comply with this Policy.

MATERIAL NONPUBLIC INFORMATION

"Material" information

Information should be regarded as material if there is a substantial likelihood that a reasonable investor would consider it important in deciding whether to buy, hold or sell securities or would view the information as significantly altering the total mix of information in the marketplace about the issuer of the security. In general, any information that could reasonably be expected to affect the market price of a security is likely to be material. Either positive or negative information may be material.

It is not possible to define all categories of "material" information. However, some examples of information that would often be regarded as material include information with respect to:

- Financial results, financial condition, earnings pre-announcements, guidance, projections or forecasts, particularly if inconsistent with the expectations of the investment community;
- Restatements of financial results, or material impairments, write-offs or restructurings;
- Changes in independent auditors, or notification that the Company may no longer rely on an audit report;
- Business plans or budgets;
- Creation of significant financial obligations, or any significant default under or acceleration of any financial obligation;
- Impending bankruptcy or financial liquidity problems;
- Significant developments involving business relationships, including execution, modification or termination of significant agreements or orders with customers, suppliers, distributors, manufacturers or other business partners;
- Clinical and development data, communications with or submissions to the U.S. Food and Drug Administration or foreign counterpart agencies, product defects, warnings, alerts or recalls or significant pricing changes or other product announcements of a significant nature;
- Therapeutic targets and product candidates;
- Significant developments relating to intellectual property;
- Significant legal or regulatory developments, whether actual or threatened;
- Major events involving the Company's securities, including calls of securities for redemption, adoption of stock repurchase programs, option repricings, stock splits, changes in dividend policies, public or private securities offerings, modification to the rights of security holders or notice of delisting;
- Significant corporate events, such as a pending or proposed merger, joint venture or tender offer, a significant investment, the acquisition or disposition of a significant business or asset or a change in control of the Company; and
- Major personnel changes, such as changes in senior management or lay-offs.

If you have any questions as to whether information should be considered "material," you should consult with a Compliance Officer. In general, it is advisable to resolve any close questions as to the materiality of any information by assuming that the information is material.

"Nonpublic" information

Information is considered nonpublic if the information has not been broadly disseminated to the public for a sufficient period to be reflected in the price of the security. Any questions as to whether information is nonpublic should be directed to a Compliance Officer.

POLICIES REGARDING MATERIAL NONPUBLIC INFORMATION

Confidentiality of nonpublic information

The unauthorized use or disclosure of nonpublic information relating to the Company or other companies is prohibited. All nonpublic information you acquire in the course of your service with the Company may only be used for legitimate company business purposes. In addition, nonpublic information of others should be handled in accordance with the terms of any relevant nondisclosure and/or Employee Proprietary Information and Inventions agreements, and the use of any such nonpublic information should be limited to the purpose for which it was disclosed.

All nonpublic information must only be used for company business purposes. You have an obligation to use all reasonable efforts to safeguard the Company's nonpublic information. You may not disclose nonpublic information about the Company, or any other company, unless required by law or unless (i) disclosure is required for legitimate Company business purposes, (ii) you are authorized to disclose the information and (iii) appropriate steps have been taken to prevent misuse of that information by the recipient (including entering into an appropriate confidentiality agreement that restricts the disclosure and use of the information, if applicable). This responsibility includes not disclosing nonpublic information in Internet discussion groups, chat rooms, bulletin boards, social media websites, blogs or other electronic media. In cases where disclosing nonpublic information to third parties is required, you should first coordinate with an attorney in the Legal Department so that appropriate confidentiality agreements can be put in place. The misuse of nonpublic information is contrary to Company policy and may also be a violation of law.

These policies are not intended to discourage employees from utilizing reporting procedures set forth in the Company's Code of Business Conduct and Ethics or Whistleblower Policy or as required by law or regulation.

No trading on material nonpublic information

Except as discussed in the section entitled "**Limited Exceptions**," you may not, directly or indirectly through others, engage in any transaction involving the Company's securities *while aware of* material nonpublic information relating to the Company. It is not an excuse that you did not "use" the information in your transaction.

Similarly, you may not engage in transactions involving the securities of any other company if you are aware of material nonpublic information about that company when that information is obtained in the course of employment with, or other services performed on behalf of, the Company (except to the extent the transactions are analogous to those presented in the section entitled "**Limited Exceptions**"). For example, you may be involved in a proposed transaction involving a prospective business relationship or transaction with another company. If information about that business relationship or transaction constitutes material nonpublic information for that other company, you would be prohibited from engaging in transactions involving the securities of that other company (as well as transactions involving the Company's securities, if that information is material to the Company). It is important to note that "materiality" is different for different companies. Information that is not material to the Company may be material to another company, and *vice versa*. You also should note that the Company's *Code of Business Conduct and Ethics* prohibits you from acquiring a financial interest in other companies if your ownership would constitute a conflict of interest.

No disclosing material nonpublic information for the benefit of others

You may not disclose material nonpublic information concerning the Company or any other company to friends, family members or any other person or entity not authorized to receive such information where such person or entity may benefit by trading on the basis of such information. In addition, you may not make recommendations or express opinions on the basis of material nonpublic information as to trading in the securities of companies to which such information relates. You are prohibited from engaging in these actions whether or not you derive any profit or personal benefit from doing so.

Obligation to disclose material nonpublic information to the Company

You may not enter into any transaction, including those discussed in the section entitled "**Limited Exceptions**," unless you have disclosed any material nonpublic information that you become aware of in the course of your service with the Company, and that senior management is not aware of, to a Compliance Officer. If you are a member of senior management, the information must be disclosed to the Chief Executive Officer, and if you are the Chief Executive Officer or a Board member, you must disclose the information to the board of directors, before any transaction is permissible.

Responding to outside inquiries for information

The Company regularly enters into Confidentiality Agreements with business entities that permit the exchange of confidential information as may be necessary for the Company to conduct its business. In the event you receive an inquiry from someone outside of the Company, such as a stock analyst, investor or reporter, for information, you should refer the inquiry to a "Designated Person" as described in the Company's Corporate Communications Policy. The Company is required under Regulation FD (Fair Disclosure) of the U.S. federal securities laws to avoid the selective disclosure of material nonpublic information. In general, the regulation provides that when a public company discloses material nonpublic information, it must provide broad, non-exclusionary access to the information. Violations of this regulation can subject the Company to SEC enforcement actions, which may result in injunctions and severe monetary penalties. The Company has established procedures for releasing material information in a manner that is designed to achieve broad public dissemination of the information immediately upon its release in compliance with applicable law. Please consult the Company's Corporate Communications Policy for more details.

TRADING BLACKOUT PERIODS

To limit the likelihood of trading at times when there is a significant risk of insider trading exposure, the Company has instituted quarterly trading blackout periods and may from time to time institute special trading blackout periods. In addition, to comply with applicable legal requirements, the Company may also institute blackout periods that prevent Board members and executive officers from trading in Company securities at a time when employees are prevented from trading Company securities in the Company's 401(k) plan.

It is important to note that whether or not you are subject to blackout periods, or whether a blackout period is currently in effect, you remain subject to the prohibitions on trading on the basis of material nonpublic information and any other applicable restrictions in this Policy.

Quarterly blackout periods

Except as discussed in the section entitled "**Limited Exceptions**," all individuals listed on **Schedule I** must refrain from conducting transactions involving the Company's securities during quarterly blackout periods.

Quarterly blackout periods begin on the 16th calendar day of the last month of each fiscal quarter (except with respect to the first quarter blackout period, which begins on the later of (i) the eighth full trading day following the date of public disclosure of the financial results for the fourth quarter of the preceding fiscal year or (ii) the 16th calendar day of the last month of the first quarter) and end at the start of the second full trading day following the date of public disclosure of the financial results for that fiscal quarter. This period is a particularly sensitive time for transactions involving the Company's securities from the perspective of compliance with applicable securities laws due to the fact that, during this period, individuals may often possess or have access to material nonpublic information relevant to the expected financial results for the quarter.

For example, the blackout period for the Company's third fiscal quarter begins on September 16 each year. For hypothetical purposes only, if in 2016, the Company were to issue its earnings release for the third quarter on Wednesday, November 2 after market close, the blackout period would then end at the start of trading on Friday, November 4 — that is, assuming you were not in possession of material nonpublic information, you would be able to trade in Company securities again beginning on November 4, 2016. For purposes of this hypothetical, the blackout period would begin on September 16, 2016 and would end at the start of the trading day on November 4, 2016.

Individuals subject to quarterly blackout periods are listed on **Schedule I**. From time to time, the Company may identify other persons who should be subject to quarterly blackout periods, and the Compliance Officers may update and revise **Schedule I** as appropriate.

The term "***trading day***" means a day on which national stock exchanges are open for trading. A "***full***" trading day has elapsed when, after the public disclosure, trading in the relevant security has opened and then closed.

Special blackout periods

From time to time, the Company may also prohibit Board members, officers, employees and designated persons from engaging in transactions involving the Company's securities when, in the judgment of a Compliance Officer, a trading blackout is warranted. The Company will generally impose special blackout periods when there are material developments known to the Company that have not yet been disclosed to the public. For example, the Company may impose a special blackout period in anticipation of announcing interim earnings guidance, clinical data or a significant transaction or business development. However, special blackout periods may be declared for any reason.

The Company will notify those persons subject to a special blackout period. Each person who has been so identified and notified by the Company may not engage in any transaction involving the Company's securities until instructed otherwise by a Compliance Officer, and should not disclose to others the fact of such suspension of trading.

Regulation BTR blackouts

Board members and executive officers may also be subject to trading blackouts pursuant to Regulation Blackout Trading Restriction, or Regulation BTR, under U.S. federal securities laws. In general, Regulation BTR prohibits any director or executive officer from engaging in certain transactions involving Company securities during periods when 401(k) plan participants are prevented from purchasing, selling or otherwise acquiring or transferring an interest in certain securities held in individual account plans. Any profits realized from a transaction that violates Regulation BTR are recoverable by the Company, regardless of the intentions of the director or officer effecting the transaction. In addition, individuals who engage in such transactions are subject to sanction by the SEC as well as potential criminal liability. When applicable, the Company will provide separate memoranda and other appropriate materials to its Board members and executive officers regarding compliance with Regulation BTR.

The Company will notify Board members and executive officers if they are subject to a blackout trading restriction under Regulation BTR. Failure to comply with an applicable trading blackout in accordance with Regulation BTR is a violation of law and this Policy.

No "**safe harbors**"

There are no unconditional "safe harbors" for trades made at particular times, and all persons subject to this Policy should exercise good judgment at all times. Even when a quarterly blackout period is not in effect, you may be prohibited from engaging in transactions involving the Company's securities because you possess material nonpublic information, are subject to a special blackout period or are otherwise restricted under this Policy.

PRE-CLEARANCE OF TRADES

Except as discussed in the section entitled "**Limited Exceptions**," Board members and officers should refrain from engaging in any transaction involving the Company's securities without first obtaining pre-clearance of the transaction from a Compliance Officer in consultation with the Chief Executive Officer (except for transactions by the Chief Executive Officer, in which case the Compliance Officer will consult with the Chairperson of the Audit Committee of the Board of Directors or the Lead Independent Director of the Board of Directors). In addition, the Company has determined that certain other employees of the Company that may have regular or special access to material nonpublic information should refrain from engaging in any transaction involving the Company's securities without first obtaining pre-clearance of the transaction from a Compliance Officer in consultation with the Chief Executive Officer. A Compliance Officer may not engage in a transaction involving the Company's securities unless the Chief Executive Officer, General Counsel (if such Compliance Officer is not General Counsel), Vice President, Finance or Chief Financial Officer has pre-cleared the transaction. In addition, a Compliance Officer may not pre-clear a transaction of any other employee in his or her department who is responsible for administering any part of this Policy. Individuals subject to pre-clearance requirements are listed on **Schedule II**. From time to time, the Company may identify other persons who should be subject to the pre-clearance requirements set forth above, and the Compliance Officers may update and revise **Schedule II** as appropriate.

These pre-clearance procedures are intended to decrease insider trading risks associated with transactions by individuals with regular or special access to material nonpublic information. In addition, requiring pre-clearance of transactions by Board members and officers facilitates compliance with Rule 144 resale restrictions under the Securities Act, the liability and reporting provisions of Section 16 under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), and Regulation BTR. Pre-clearance of a trade, however, is not a defense to a claim of insider trading and does not excuse you from otherwise complying with insider trading laws or this Policy.

The Compliance Officers are under no obligation to approve a transaction submitted for pre-clearance, and in their sole discretion may determine not to permit the transaction.

COMPLIANCE WITH SECTION 16 OF THE SECURITIES EXCHANGE ACT

Obligations under Section 16

Section 16 of the Exchange Act, and the related rules and regulations, set forth (i) reporting obligations, (ii) limitations on "short-swing" transactions and (iii) limitations on short sales and other transactions applicable to Board members, executive officers, large shareholders and certain other persons. The Company has provided, or will provide, memoranda and other materials addressing these matters.

The Company has determined that those persons listed on **Schedule III** are required to comply with Section 16 of the Exchange Act, and the related rules and regulations, because of their positions with the Company. The Compliance Officers may amend **Schedule III** from time to time as appropriate to reflect the election of new executive officers or Board members, any change in the responsibilities of executive officers or other employees and any promotions, demotions, resignations or departures.

Schedule III is not necessarily an exhaustive list of persons subject to Section 16 requirements at any given time. Even if you are not listed on **Schedule III**, you may be subject to Section 16 reporting obligations because of your shareholdings, for example.

Notification requirements to facilitate Section 16 reporting

To facilitate timely reporting of transactions pursuant to Section 16 requirements, each person subject to Section 16 reporting requirements must provide, or must ensure that his or her broker provides, the Company with detailed information (*e.g.,* trade date, number of shares, exact price, *etc.*) regarding his or her transactions involving the Company's securities, including gifts, transfers, pledges and transactions pursuant to a trading plan, both prior to (to confirm compliance with pre-clearance procedures, if applicable) and promptly following execution.

Personal responsibility

The obligation to file Section 16 reports, and to otherwise comply with Section 16, is personal. The Company is not responsible for the failure to comply with Section 16 requirements.

ADDITIONAL RESTRICTIONS AND GUIDANCE

This section addresses certain types of transactions that may expose you and the Company to significant risks. You should understand that, even though a transaction may not be expressly prohibited by this section, you are responsible for ensuring that the transaction otherwise complies with other provisions in this Policy that may apply to the transaction, such as the general prohibition against insider trading as well as pre-clearance procedures and blackout periods, to the extent applicable.

Short sales

Short sales (*i.e.,* the sale of a security that must be borrowed to make delivery) and "selling short against the box" (*i.e.,* a sale with a delayed delivery) with respect to Company securities are prohibited under this Policy. Short sales may signal to the market possible bad news about the Company or a general lack of confidence in the Company's prospects, and an expectation that the value of the Company's securities will decline. In addition, short sales are effectively a bet against the Company's success and may reduce the seller's incentive to improve the Company's performance. Short sales may also create a suspicion that the seller is engaged in insider trading.

Derivative securities and hedging transactions

Transactions in publicly-traded options, such as puts and calls, and other derivative securities with respect to the Company's securities are prohibited under this Policy. Transactions in derivative securities may reflect a short-term and speculative interest in the Company's securities and may create the appearance of impropriety, even where a transaction does not involve trading on inside information. Trading in derivatives may also focus attention on short-term performance at the expense of the Company's long-term objectives. This prohibition extends to any hedging or similar transaction designed to decrease the risks associated with holding Company securities. Stock options, stock appreciation rights and other securities issued pursuant to Company benefit plans or other compensatory arrangements with the Company are not subject to this prohibition.

Using Company securities as collateral for loans

If you are required to comply with Section 16 of the Exchange Act or pre-clearance requirements under this Policy (*i.e.,* if you are listed on **Schedule II** or **III**), you may not pledge Company securities as collateral for loans unless such pledge is approved in accordance with the "Pledge/Margin Pre-Approval Process" set forth below. If you default on the loan, the lender typically is permitted to sell the pledged securities as collateral in a foreclosure sale. The sale, even though not initiated at your request, is still considered a sale for your benefit under securities laws and, if made at a time when you are aware of material nonpublic information or otherwise are not permitted to trade in Company securities, may result in inadvertent insider trading violations, Section 16 and Regulation BTR violations (for executive officers and Board members), violations of this Policy and unfavorable publicity for you and the Company. For example, if a sale occurs during a regular quarterly blackout period, you will be in violation of this Policy. For these same reasons, even if you are not prohibited from pledging Company securities as collateral for loans, you should exercise significant caution when doing so.

Holding Company securities in margin accounts

If you are required to comply with Section 16 of the Exchange Act or pre-clearance requirements under this Policy (*i.e.,* if you are listed on **Schedule II** or **III**), you may not hold Company securities in margin accounts in which Company securities may be sold without your consent unless such arrangement is approved in accordance with the "Pledge/Margin Account Pre-Approval Process" set forth below. Under typical margin arrangements, if you fail to meet a margin call, the broker may be entitled to sell securities held in the margin account without your consent. The sale, even though not initiated at your request, is still considered a sale for your benefit under securities laws and, if made at a time when you are aware of material nonpublic information or are otherwise not permitted to trade, may result in inadvertent insider trading violations, Section 16 and Regulation BTR violations (for executive officers and Board members), violations of this Policy and unfavorable publicity for you and the Company. For example, if a sale occurs during a regular quarterly blackout period, you will be in violation of this Policy. For these same reasons, even if you are not prohibited from holding Company securities in margin accounts, you should exercise significant caution when doing so.

Placing open orders with brokers

Except in accordance with an approved trading plan (as discussed below), you should exercise caution when placing open orders, such as limit orders or stop orders, with brokers, particularly where the order is likely to remain outstanding for an extended period of time. Open orders may result in the execution of a trade at a time when you are aware of material nonpublic information or otherwise are not permitted to trade in Company securities, which may result in inadvertent insider trading violations, Section 16 and Regulation BTR violations (for executive officers and Board members), violations of this Policy and unfavorable publicity for you and the Company. You should inform any broker with whom you place any open order at the time it is placed that you are subject to this Policy and its blackout periods (and pre-clearance requirements, if applicable).

Pledge/Margin Account Pre-Approval Process

An exception to the above prohibitions on pledging Company securities as collateral for loans and holding Company securities in margin accounts may be granted in limited circumstances where a person wishes to pledge Company securities as collateral for a loan (but not including margin debt) and clearly demonstrates the financial capacity to repay the loan without resort to the pledged securities. Any person who wishes to pledge Company securities as collateral for a loan must submit a request for approval to a Compliance Officer, sufficiently in advance (at least two weeks) to enable evaluation of the pledge arrangement and, prior to the proposed execution of documents evidencing the proposed pledge:

- with respect to a proposed pledge by the Chief Executive Officer or any other executive officer, any Board member or any Compliance Officer, to obtain approval from the Board of Directors or the Audit Committee of the Board of Directors; or

- with respect to a proposed pledge by any other person subject to the pre-clearance requirements under this Policy (i.e., listed on **Schedule II** or **III**), to obtain approval from a Compliance Officer in consultation with (i) the Chief Executive Officer and (ii) either the Board of Directors or the Audit Committee of the Board of Directors.

LIMITED EXCEPTIONS

The following are certain limited exceptions to the restrictions imposed by the Company under this Policy. Please be aware that even if a transaction is subject to an exception to this Policy, you will need to separately assess whether the transaction complies with applicable law. For example, even if a transaction is indicated as exempt from this Policy, you may need to comply with the "short-swing" trading restrictions under Section 16 of the Exchange Act, to the extent applicable. You are responsible for complying with applicable law at all times.

Transactions pursuant to a trading plan that complies with SEC rules

The SEC has enacted rules that provide an affirmative defense against alleged violations of U.S. federal insider trading laws for transactions pursuant to trading plans that meet certain requirements. In general, the affirmative defense provided by Rule 10b5-1 under the Exchange Act will apply if you enter into a contract, provide instructions or adopt a written plan for trading securities in good faith and when you are not aware of material nonpublic information. The contract, instructions or plan must (i) specify the amount, price and date of the transaction, (ii) specify an objective method for determining the amount, price and date of the transaction and/or (iii) place any subsequent discretion for determining the amount, price and date of the transaction in another person who is not, at the time of the transaction, aware of material nonpublic information.

Transactions made pursuant to a written trading plan that (i) complies with the affirmative defense set forth in Rule 10b5-1 and (ii) has been provided to a Compliance Officer in the legal department for review prior to adoption or modification, are not subject to the restrictions in this Policy against trades made while aware of material nonpublic information or to the pre-clearance procedures or blackout periods established under this Policy. In reviewing a trading plan (including modifications to a trading plan), a Compliance Officer may, consistent with and in furtherance of the objectives expressed in this Policy, impose criteria in addition to those set forth in Rule 10b5-1. You must provide the Compliance Officer a reasonable amount of time, at least two weeks, to review any proposed new or modified trading plan.

The SEC rules regarding trading plans are complex and must be complied with completely to be effective. The description provided above is only a summary, and the Company strongly advises that you consult with your legal advisor if you intend to adopt a trading plan. While trading plans are subject to review by the Company, the individual adopting the trading plan is ultimately responsible for compliance with Rule 10b5-1 and ensuring that the trading plan complies with this Policy.

Following the review of a trading plan by a Compliance Officer, the executed trading plan, including proposed modifications to the trading plan, must be filed with a Compliance Officer in the legal department and must be accompanied by an executed certificate stating that the trading plan complies with Rule 10b5-1 and any other criteria established by the Company. The Company may, and, in the case of Board members and executive officers must to the extent required by applicable law, publicly disclose information regarding trading plans that you may enter into, modify or terminate. Attached as Annex A to this Policy are guidelines for preparing a trading plan and the minimum requirements that any trading plan must meet to comply with this Policy. The Compliance Officers may impose additional requirements consistent with and in furtherance of the objectives expressed in this Policy.

Receipt and vesting of stock options, restricted stock and stock appreciation rights

The trading restrictions under this Policy do not apply to the acceptance or purchase of stock options, restricted stock or stock appreciation rights issued or offered by the Company. The trading restrictions under this Policy also do not apply to the vesting, cancellation or forfeiture of stock options, restricted stock or stock appreciation rights in accordance with applicable plans and agreements.

Exercise of stock options for cash

The trading restrictions under this Policy do not apply to the exercise of stock options for cash under the Company's stock option plans. Likewise, the trading restrictions under this Policy do not apply to the exercise of stock options in a stock-for-stock exercise with the Company or an election to have the Company withhold securities to cover tax obligations in connection with an option exercise. However, the trading restrictions under this Policy do apply (i) to the sale of any securities issued upon the exercise of a stock option, (ii) to a cashless exercise of a stock option through a broker, since this involves selling a portion of the underlying shares to cover the costs of exercise, and (iii) to any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Certain 401(k) plan transactions

Although the Company currently does not offer its employees the ability to purchase or sell Company stock in a 401(k) plan, if the Company does offer this ability in the future these trading restrictions will not apply to purchases of Company stock in the 401(k) plan resulting from periodic contributions to the plan based on your payroll contribution election. The trading restrictions will apply, however, to elections you may make under the 401(k) plan (i) to increase or decrease the percentage of your contributions that will be allocated to a Company stock fund, (ii) to move balances into or out of a Company stock fund, (iii) to borrow money against your 401(k) plan account if the loan will result in liquidation of some or all of your Company stock fund balance, and (iv) to pre-pay a plan loan if the pre-payment will result in the allocation of loan proceeds to a Company stock fund.

Stock splits, stock dividends and similar transactions

The trading restrictions under this Policy do not apply to a change in the number of securities held as a result of a stock split or stock dividend applying equally to all securities of a class, or similar transactions.

***Bona fide* gifts and inheritance**

The trading restrictions under this Policy do not apply to *bona fide* gifts involving Company securities or transfers by will or the laws of descent and distribution.

Change in form of ownership

Transactions that involve merely a change in the form in which you own securities are permissible. For example, you may transfer shares to an *inter vivos* trust of which you are the sole beneficiary during your lifetime.

Other exceptions

Any other exception from this Policy must be approved by a Compliance Officer, in consultation with the Board of Directors or an independent committee of the Board of Directors.

ADDITIONAL INFORMATION

Delivery of Policy

This Policy will be delivered to all Board members, officers, employees and designated persons of the Company when they commence service with the Company. In addition, this Policy (or a summary of this Policy) will be circulated periodically. Each Board member, officer, employee and designated person of the Company is required to acknowledge that he or she understands, and agrees to comply with, this Policy. Any failure to provide such an acknowledgment will not relieve the Board member, officer, employee or designated person from the obligation to comply with this Policy.

Amendments

We are committed to continuously reviewing and updating our policies and procedures. The Company therefore reserves the right to amend, alter or terminate this Policy at any time and for any reason, subject to applicable law. A current copy of the Company's policies regarding insider trading may be obtained by contacting a Compliance Officer.

* * *

Nothing in this Insider Trading Policy creates or implies a contractual right, an employment contract or term of employment. Employment at the Company is employment at-will. Employment at-will may be terminated with or without cause and with or without notice at any time by the employee or the Company. Nothing in this Insider Trading Policy shall limit the right to terminate employment at-will. No employee of the Company has any authority to enter into any agreement for employment for a specified period of time or to make any agreement or representation contrary to the Company's policy of employment at-will. Only the Chief Executive Officer of the Company has the authority to make any such agreement, which must be in writing.

The policies in this Insider Trading Policy do not constitute a complete list of company policies or a complete list of the types of conduct that can result in discipline, up to and including discharge.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-162732) pertaining to the Omeros Corporation 2008 Equity Incentive Plan, Omeros Corporation Second Amended and Restated 1998 Stock Option Plan, nura, Inc. 2003 Stock Option Plan, Stock Option Grant to Gregory A. Demopulos, M.D., and Stock Option Grant to Pamela Pierce Palmer, M.D., Ph.D,

(2) Registration Statement (Form S-8 No. 333-165861) pertaining to the Omeros Corporation 2008 Equity Incentive Plan,

(3) Registration Statement (Form S-8 No. 333-172905) pertaining to the Omeros Corporation 2008 Equity Incentive Plan,

(4) Registration Statement (Form S-8 No. 333-180216) pertaining to the Omeros Corporation 2008 Equity Incentive Plan,

(5) Registration Statement (Form S-8 No. 333-187344) pertaining to the Omeros Corporation 2008 Equity Incentive Plan,

(6) Registration Statement (Form S-8 No. 333-194693) pertaining to the Omeros Corporation 2008 Equity Incentive Plan,

(7) Registration Statement (Form S-8 No. 333-202788) pertaining to the Omeros Corporation 2008 Equity Incentive Plan,

(8) Registration Statement (Form S-8 No. 333-210219) pertaining to the Omeros Corporation 2008 Equity Incentive Plan,

(9) Registration Statement (Form S-8 No. 333-216749) pertaining to the Omeros Corporation 2008 Equity Incentive Plan,

(10) Registration Statement (Form S-8 No. 333-218882) pertaining to the Omeros Corporation 2017 Omnibus Incentive Compensation Plan,

(11) Registration Statement (Form S-8 No. 333-232071) pertaining to the Omeros Corporation 2017 Omnibus Incentive Compensation Plan,

(12) Registration Statement (Form S-8 No. 333-257148) pertaining to the Omeros Corporation 2017 Omnibus Incentive Compensation Plan

(13) Registration Statement (Form S-8 No. 333-273855) pertaining to the Omeros Corporation 2017 Omnibus Incentive Compensation Plan, and

(14) Registration Statement (Form S-3 No. 333- 268269) of Omeros Corporation

of our report dated March 31, 2025, with respect to the consolidated financial statements of Omeros Corporation included in this Annual Report (Form 10-K) of Omeros Corporation for the year ended December 31, 2024.

/s/ Ernst & Young LLP

Seattle, Washington
March 31, 2025

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gregory A. Demopulos, M.D., certify that:

1. I have reviewed this annual report on Form 10-K of Omeros Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 31, 2025

/s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D.
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a)/15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David J. Borges, certify that:

1. I have reviewed this annual report on Form 10-K of Omeros Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 31, 2025

/s/ David J. Borges
David J. Borges
Principal Financial and Accounting Officer

Exhibit 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

In connection with the annual report on Form 10-K of Omeros Corporation (the "Company") for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Dated: March 31, 2025

/s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D.
Principal Executive Officer

Exhibit 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

In connection with the annual report on Form 10-K of Omeros Corporation (the "Company") for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Dated: March 31, 2025

/s/ David J. Borges
David J. Borges
Principal Financial and Accounting Officer