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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019
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)	**(Zip Code)**

(206) 676-5000
(Registrant's telephone number, including area code)

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Securities Registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

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

As of November 8, 2019, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 49,747,818.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 information currently available to our management. 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," "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 expectations related to obtaining permanent separate or similar reimbursement for OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% from the Centers for Medicare & Medicaid Services (CMS) for periods after September 30, 2020, and our expectations regarding reimbursement coverage for OMIDRIA by commercial and government payers;

- our estimates regarding how long our existing cash, cash equivalents, short-term investments and revenues will be sufficient to fund our anticipated operating expenses, capital expenditures and debt service obligations;

- our expectations relating to demand for OMIDRIA from wholesalers, ambulatory surgery centers (ASCs) and hospitals, and our expectations regarding OMIDRIA product sales;

- our plans for the marketing and distribution of OMIDRIA and our estimates of OMIDRIA chargebacks and rebates, distribution fees and product returns;

- our expectations regarding the clinical, therapeutic and competitive benefits and importance of OMIDRIA and our product candidates;

- our ability to design, initiate and/or successfully complete clinical trials and other studies for our products and product candidates and our plans and expectations regarding our ongoing or planned clinical trials, including for our lead MASP-2 inhibitor, narsoplimab (also referred to as OMS721), and for our other investigational candidates, including OMS527 and OMS906;

- with respect to our narsoplimab clinical programs, our expectations regarding: whether enrollment in any or all ongoing and planned Phase 3 and Phase 2 clinical trials will proceed as expected; whether we can capitalize on the financial and regulatory incentives provided by orphan drug designations granted by the U.S. Food and Drug Administration (FDA), the European Commission (EC), or the European Medicines Agency (EMA); and whether we can capitalize on the regulatory incentives provided by fast-track and/or breakthrough therapy designations granted by the FDA;

- our expectations regarding clinical plans and anticipated or potential paths to regulatory approval of narsoplimab by the FDA and/or EMA in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), Immunoglobulin A (IgA) nephropathy, and atypical hemolytic uremic syndrome (aHUS);

- whether and when a Biologics License Application (BLA) may be filed with the FDA for narsoplimab in any indication, whether the FDA will grant approval for narsoplimab in any indication, and whether any such approval will be accelerated or regular (full) approval;

- whether and when a marketing authorization application (MAA) may be filed with the EMA for narsoplimab in any indication, and whether the EMA will grant approval for narsoplimab in any indication;

- our plans for the commercial launch of narsoplimab following any regulatory approval and our estimates and expectations regarding coverage and reimbursement for any approved products;

- our expectation that we will rely on contract manufacturers to manufacture OMIDRIA for commercial sale and to manufacture our product candidates for purposes of clinical supply and in anticipation of potential commercialization;

- our ability to raise additional capital through the capital markets or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;

- our expectations about the commercial competition that OMIDRIA and our product candidates, if commercialized, face or may face;

- the expected course and costs of existing claims, legal proceedings and administrative actions, our involvement in 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, products 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 this Quarterly Report on Form 10-Q under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in our other filings with the U.S. 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, 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 Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable law, 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.

OMEROS CORPORATION
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2019

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

OMEROS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 8,861	$ 5,861
Short-term investments	18,481	54,637
Receivables, net	29,931	22,818
Inventory	1,173	88
Prepaid expense and other assets	5,353	6,463
Total current assets	63,799	89,867
Property and equipment, net	3,787	3,845
Right of use assets	21,302	—
Restricted investments	1,154	1,154
Advanced payments, non-current	1,221	1,070
Total assets	$ 91,263	$ 95,936
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$ 9,702	$ 6,281
Accrued expenses	33,996	30,186
Current portion of lease liabilities	3,055	889
Total current liabilities	46,753	37,356
Lease liabilities, non-current	28,654	1,578
Unsecured convertible senior notes, net	155,771	148,981
Deferred rent	—	8,177
Commitments and contingencies (Note 8)		
Shareholders' deficit:		
Preferred stock, par value $0.01 per share, 20,000,000 shares authorized; none issued and outstanding at September 30, 2019 and December 31, 2018.	—	—
Common stock, par value $0.01 per share, 150,000,000 shares authorized at September 30, 2019 and December 31, 2018; 49,525,474 and 49,011,684 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively.	495	490
Additional paid-in capital	564,976	549,479
Accumulated deficit	(705,386)	(650,125)
Total shareholders' deficit	(139,915)	(100,156)
Total liabilities and shareholders' deficit	$ 91,263	$ 95,936

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product sales, net	$ 29,856	$ 4,608	$ 78,389	$ 7,852
Costs and expenses:				
Cost of product sales	278	36	464	355
Research and development	23,746	26,862	69,108	64,414
Selling, general and administrative	16,933	13,152	48,493	36,830
Total costs and expenses	40,957	40,050	118,065	101,599
Loss from operations	(11,101)	(35,442)	(39,676)	(93,747)
Interest expense	(5,715)	(4,602)	(16,846)	(11,104)
Other income	353	572	1,261	1,628
Net loss	$ (16,463)	$ (39,472)	$ (55,261)	$ (103,223)
Comprehensive loss	$ (16,463)	$ (39,472)	$ (55,261)	$ (103,223)
Basic and diluted net loss per share	$ (0.33)	$ (0.81)	$ (1.12)	$ (2.13)
Weighted-average shares used to compute basic and diluted net loss per share	49,373,156	48,647,416	49,157,055	48,437,870

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2019	2018
Operating activities:		
Net loss	$ (55,261)	$ (103,223)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	10,468	8,896
Non-cash interest expense	6,790	4,308
Depreciation and amortization	1,262	654
Changes in operating assets and liabilities:		
Receivables	(7,113)	14,847
Inventory	(1,085)	229
Prepaid expenses and other assets	959	(2,608)
Accounts payable and accrued expenses	6,921	(2,183)
Net cash used in operating activities	(37,059)	(79,080)
Investing activities:		
Purchases of property and equipment	(318)	(474)
Purchases of investments	(594)	(45,514)
Proceeds from the sale and maturities of investments	36,750	73,500
Net cash provided by investing activities	35,838	27,512
Financing activities:		
Proceeds from borrowings under notes payable	—	44,550
Proceeds upon exercise of stock options and warrants	5,034	6,720
Release in restricted investments	—	56
Payments on finance lease liabilities	(813)	(365)
Net cash provided by financing activities	4,221	50,961
Net increase (decrease) in cash and cash equivalents	3,000	(607)
Cash and cash equivalents at beginning of period	5,861	3,394
Cash and cash equivalents at end of period	$ 8,861	$ 2,787
Supplemental cash flow information		
Cash paid for interest	$ 6,811	$ 6,796
Conversion of accrued interest to notes payable	$ —	$ 3,246
Fair value of warrants issued in connection with notes payable amendment	$ —	$ 1,424
Property acquired under finance lease	$ 886	$ 579

See accompanying Notes to Condensed Consolidated Financial Statements

OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, complement-mediated diseases, disorders of the central nervous system, and immune-related diseases, including cancers. Our first drug product, OMIDRIA, is marketed in the United States (U.S.) for use during cataract surgery or intraocular lens replacement.

Basis of Presentation

Our condensed consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions have been eliminated and we have determined we operate in one segment. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of September 30, 2019 and December 31, 2018 and for the three and nine months ended September 30, 2019 and 2018 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2018 has been derived from our audited financial statements but does not include all of the information and footnotes required by GAAP for audited annual financial information.

The accompanying unaudited condensed consolidated financial statements and related notes thereto should be read in conjunction with the audited consolidated financial statements and related notes thereto that are included in our Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 1, 2019.

We continue to advance a series of clinical and preclinical programs (including three programs currently in Phase 3). The Centers for Medicare & Medicaid Services (CMS) granted transitional pass-through reimbursement status for OMIDRIA from January 1, 2015 through December 31, 2017 for patients covered by Medicare Part B. On October 1, 2018, OMIDRIA pass-through reimbursement was reinstated for a two-year period. In its 2020 outpatient prospective payment system (OPPS) final rule, issued on November 1, 2019, CMS declined to grant separate payment to OMIDRIA beyond the expiration of its current pass-through status on September 30, 2020. CMS also noted in the 2020 final rule that it would continue to analyze evidence and monitor utilization of OMIDRIA. We cannot at this time predict with precision future OMIDRIA revenues due to the uncertain impact of the 2020 OPPS final rule on sales of OMIDRIA in 2019 and 2020. As a result, despite our record OMIDRIA sales over consecutive quarters, meaningful growth in OMIDRIA sales in the fourth quarter 2019 and 2020 are not included in the determination regarding our prospects as a going concern. Similarly, we are unable to include in the determination amounts available under our revolving line of credit or any proceeds from debt transactions or other financing instruments despite our successful track record in accessing capital through these avenues. We also have not included any potential partnerships related to our products or product candidates. The conditions described above, when evaluated within the constraints of the accounting literature, raise substantial doubt with respect to our ability to meet our obligations through November 12, 2020 and, therefore, to continue as a going concern.

We plan to continue to fund a portion of our operations through proceeds from sales of OMIDRIA and, if necessary, through other revenue sources and financial instruments as noted above. If these capital sources, for any reason, are needed but inaccessible, it would have a significantly negative effect our financial condition. Should it be necessary to manage our operating expenses, we would reduce our projected cash requirements through reduction of our

expenses by delaying clinical trials, reducing selected research and development efforts, and/or implementing other restructuring activities.

The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. 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.

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 revenue recognition, stock-based compensation expense and accruals for clinical trials, manufacturing of drug product and clinical drug supply and contingencies. 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.

Revenue Recognition

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

Product Sales, Net

We generally record revenue from product sales when the product is delivered to our wholesalers. Product sales are recorded net of wholesaler distribution fees and estimated chargebacks, rebates, returns and purchase-volume discounts. Accruals or allowances are established for these deductions in the same period when revenue is recognized, and actual amounts incurred are offset against the applicable accruals or allowances. We reflect each of these accruals or allowances as either a reduction in the related accounts receivable or as an accrued liability depending on how the amount is expected to be settled.

Right-of-Use Assets and Related Lease Liabilities

On January 1, 2019, we adopted Accounting Standards Update (ASU) 2016-02,*Leases*, (Topic 842) using a modified retrospective approach versus recasting the prior periods presented. We elected the package of practical expedients permitted under the transition guidance, which allowed us to carryforward our historical assessment of whether (i) contracts contain leases, (ii) lease classifications and (iii) initial direct costs. Upon adoption we recognized right-of-use assets and lease liabilities of $17.7 million and $26.4 million, respectively, in our Consolidated Balance Sheet. The balance of the net right-of-use asset included the reversal of the outstanding balance of deferred rent of $8.7 million.

We record operating leases on our Consolidated Balance Sheet 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 leases on our Consolidated Balance Sheet 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 a finance lease 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 operating expenses on a straight-line basis over the lease term.

Advance Payments

Advance payments for goods or services that will be used or rendered 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, or when the goods or services are no longer expected to be provided.

Stock-Based Compensation

On January 1, 2019, we adopted ASU 2018-07,*Compensation — Stock Compensation,* (Topic 958) which simplifies the accounting for share-based payments granted to non-employees for services by aligning it with the accounting for share-based payments to employees and directors, with certain exceptions. The adoption was immaterial to our consolidated financial statements.

Stock-based compensation expense is recognized for all share-based payments based on estimated fair values as of the date of grant. The fair value of our stock options is calculated using the Black-Scholes option-pricing model which requires judgmental assumptions including volatility, forfeiture rates and expected option life. We use the straight-line method to allocate stock-based compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period.

Recent Accounting Pronouncement Not Yet Adopted

In June 2016, the Financial Accounting Standards Board issued ASU 2016-13,*Financial Instruments — Credit Losses,* (Topic 326) which changes how entities account for credit losses on most financial assets and certain other instruments, and expands disclosures. The standard is effective for annual and interim periods beginning after December 15, 2019 with early adoption permitted. We expect to adopt the standard on January 1, 2020 and are still in process of evaluating the effect of adoption on our consolidated financial statements and disclosures.

Note 2—Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common share equivalents outstanding for the period, determined using the treasury-stock method. Common share equivalents are excluded from the diluted net loss per share computation if their effect is anti-dilutive.

The basic and diluted net loss per share amounts for the three and nine months ended September 30, 2019 and 2018 were computed based on the shares of common stock outstanding during the respective periods. Potentially dilutive securities excluded from the diluted loss per share calculation are as follows:

	September 30,	
	2019	**2018**
Outstanding options to purchase common stock	11,494,722	10,123,530
Outstanding warrants to purchase common stock	243,115	243,115
Total potentially dilutive shares excluded from loss per share	11,737,837	10,366,645

Note 3—Certain Balance Sheet Accounts

Accounts Receivable, net

Accounts receivable, net consist of the following:

	September 30, 2019	December 31, 2018
	(In thousands)	
Trade receivables, net	$ 29,809	$ 22,654
Sublease and other receivables	122	164
Total accounts receivables, net	$ 29,931	$ 22,818

Trade receivables are shown net of $1.5 million and $0.4 million of chargeback and product return allowances as of September 30, 2019 and December 31, 2018, respectively.

Inventory

Inventory consists of the following:

	September 30, 2019	December 31, 2018
	(In thousands)	
Raw materials	$ 43	$ 83
Work-in-progress	379	—
Finished goods	751	5
Total inventory	$ 1,173	$ 88

Property and Equipment, Net

Property and equipment, net consists of the following:

	September 30, 2019	December 31, 2018
	(In thousands)	
Finance leases	$ 4,920	$ 4,034
Laboratory equipment	2,828	2,569
Computer equipment	921	862
Office equipment and furniture	625	625
Total cost	9,294	8,090
Less accumulated depreciation and amortization	(5,507)	(4,245)
Total property and equipment, net	$ 3,787	$ 3,845

For the nine months ended September 30, 2019 and 2018, depreciation and amortization expenses were $1.3 million and $0.7 million, respectively.

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2019	December 31, 2018
	(In thousands)	
Contract research and development	$ 10,559	$ 12,012
Sales rebates, fees and discounts	9,691	8,075
Interest payable	4,922	1,677
Employee compensation	3,371	2,714
Consulting and professional fees	3,162	3,669
Clinical trials	1,432	820
Other accrued expenses	859	1,219
Total accrued expenses	$ 33,996	$ 30,186

Note 4—Fair-Value Measurements

As of September 30, 2019, and December 31, 2018, all investments were classified as short-term and available-for-sale on the accompanying Condensed Consolidated Balance Sheets. Investment income, which was included as a component of other income, consists of interest earned.

On a recurring basis, we measure certain financial assets at fair value. 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 and liabilities measured at fair value on a recurring basis are as follows:

	September 30, 2019			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	$ 1,154	$ —	$ —	$ 1,154
Money-market funds classified as short-term investments	18,481	—	—	18,481
Total	$ 19,635	$ —	$ —	$ 19,635

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	$ 1,154	$ —	$ —	$ 1,154
Money-market funds classified as short-term investments	54,637	—	—	54,637
Total	$ 55,791	$ —	$ —	$ 55,791

Cash held in demand deposit accounts of $8.9 million and $5.9 million is excluded from our fair-value hierarchy disclosure as of September 30, 2019 and December 31, 2018, respectively. There were no unrealized gains or losses associated with our short-term investments as of September 30, 2019 or December 31, 2018. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets for receivables, accounts payable, other current monetary assets and liabilities approximate fair value.

Note 5—Debt

2016 CRG Loan Agreement

In 2016, we entered into a term loan agreement with CRG Servicing LLC (the CRG Loan) and borrowed $80.0 million thereunder. In May 2018, we borrowed the remaining $45.0 million available under the CRG Loan and issued warrants to purchase up to 200,000 shares of our common stock with an exercise price of $23.00 per share. The warrants have a five-year term and remained outstanding as of September 30, 2019.

In November 2018, we issued $210.0 million in principal amount of unsecured convertible senior notes (see Note 6 - “Convertible Senior Notes”) and repaid the CRG Loan. Upon repayment, we incurred a loss on early extinguishment of debt of $13.0 million.

2019 Silicon Valley Bank Line of Credit Agreement

On August 2, 2019, we entered into a Loan and Security Agreement with Silicon Valley Bank (the Loan Agreement), which provides for a $50.0 million revolving line of credit facility. Under the Loan Agreement we may draw, on a revolving basis, up to the lesser of $50.0 million and 85.0% of our eligible accounts receivable, less certain reserves. The Loan Agreement is secured by all our assets excluding intellectual property and development program inventories and matures on August 2, 2022.

Interest on amounts outstanding is payable monthly at a floating rate equal to the greater of 5.50% and the prime rate per annum. If the Loan Agreement is terminated prior to the maturity date for any reason other than replacement with a new Silicon Valley Bank (SVB) credit facility or a new syndicated facility in which SVB acts as the agent, we are required to pay a termination fee equal to 2.0% of the revolving line facility (or $1.0 million). We paid an initial commitment fee of $150,000 upon closing and are required to pay additional commitment fees of $150,000 on each of the first and second anniversaries of the closing date, or upon the earlier termination of, or default under, the Loan Agreement.

The Loan Agreement requires a lockbox arrangement whereby our trade accounts receivable collections are deposited into a control account. Amounts deposited in the account are transferred daily to our operating account, except that during periods of reduced liquidity or upon an event of default, the amounts received in the control account are applied to reduce the outstanding obligations under the Loan Agreement. The Loan Agreement includes customary events of default that include, among other things, breach, non-payment, inaccuracy of representations and warranties, the occurrence of a material adverse change in our business or prospects for repayment of the loan, cross default to material indebtedness or material agreements, bankruptcy and insolvency, material judgments and a change in control. In the event of default, SVB may require all obligations under the Loan Agreement to be immediately due and payable and charge a default rate of interest thereon.

As of September 30, 2019, we had no outstanding borrowings under the Loan Agreement.

Note 6—Convertible Senior Notes

On November 15, 2018, we issued at face value $210.0 million aggregate principal amount of our 6.25% Convertible Senior Notes due 2023 (the Convertible Notes). The Convertible Notes are unsecured and accrue interest at an annual rate of 6.25% per annum, payable semi-annually in arrears on May 15 and November 15 of each year, beginning on May 15, 2019.

The Convertible Notes will be convertible into cash, shares of our common stock or a combination thereof, as we elect at our sole discretion. The initial conversion rate is 52.0183 shares of our common stock per $1,000 of note principal (equivalent to an initial conversion price of approximately $19.22 per share of common stock), subject to adjustment in certain circumstances. As of September 30, 2019, all Convertible Notes remain outstanding.

The balance of our Convertible Notes at September 30, 2019 and December 31, 2018, is as follows:

	September 30, 2019	December 31, 2018
	(In thousands)	
Principal amount	$ 210,000	$ 210,000
Unamortized discount	(49,907)	(56,156)
Unamortized issuance costs attributable to principal amount	(4,322)	(4,863)
Total Convertible Notes, net	$ 155,771	$ 148,981

For more details on our Convertible Notes see Part II, Item 8, Note 8 - “Convertible Senior Notes” in our Annual Report on Form 10-K for the year ended December 31, 2018.

Note 7—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 December 2023.

As described further in Note 1 – "Organization and Significant Accounting Policies", on January 1, 2019, we adopted ASU 2016-02, *Leases*, (Topic 842) using a modified retrospective approach versus recasting the prior periods presented. The lease-related assets and liabilities recorded on the balance sheet are as follows. Prior year interim financial statements were not recast under the new standard and, therefore, those amounts are not presented below.

	Classification on the Balance Sheet	September 30, 2019 (In thousands)
Assets		
Operating lease assets	Right of use assets	$ 21,302
Finance lease assets	Property and equipment, net	2,774
Total lease assets		$ 24,076
Liabilities		
Current:		
Operating leases	Current portion of lease liabilities	$ 1,927
Finance lease	Current portion of lease liabilities	1,128
Non-current:		
Operating	Lease liability, non-current	27,242
Finance	Lease liability, non-current	1,412
Total lease liabilities		$ 31,709
Weighted-average remaining lease term		
Operating leases		8.1 years
Finance leases		2.4 years
Weighted-average discount rate		
Operating leases		12.85 %
Finance leases		12.26 %

The components of total lease costs are as follows:

	Nine Months Ended September 30, 2019 (In thousands)
Lease cost	
Operating lease cost	$ 3,121
Finance lease cost:	
Amortization	984
Interest	248
Short-term lease cost	275
Variable lease cost	1,424
Sublease income	(673)
Total lease cost	$ 5,379

The supplemental cash flow information related to leases during 2019 is as follows:

Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flows used for operating leases	$ 4,962
Operating cash flows used for finance leases	$ 248
Financing cash flows used for finance leases	$ 813

The future maturities of our lease liabilities as of September 30, 2019 are as follows:

	Operating Leases	Finance Leases
	(In thousands)	
2019	$ 1,358	$ 342
2020	5,755	1,248
2021	5,826	889
2022	5,898	296
2023	5,972	95
Thereafter	23,102	—
Total undiscounted lease payments	47,911	2,870
Less interest	18,742	330
Lease liabilities	$ 29,169	$ 2,540

In September 2019, we recognized a new lease component associated with additional office space in our headquarters building and recorded additional lease liability of $3.7 million. In October 2019, we leased additional office and laboratory space in our headquarters building and recorded the associated lease liability of $3.9 million.

Note 8—Commitments and Contingencies

Contracts

We have various agreements with third parties that would collectively require payment of termination fees totaling $22.6 million as of September 30, 2019 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 licensed a variety of intellectual property from third parties that we are currently developing or may develop in the future. These licenses may require milestone payments during clinical development as well as low single to low double-digit royalties on the net income or net sales of the product. For the three and nine months ended September 30, 2019 and the year ended December 31, 2018, development milestones incurred were insignificant and we did not owe any royalties.

Note 9—Shareholders' Deficit

Common Stock

For the nine months ended September 30, 2019, we received proceeds of $5.0 million upon the exercise of stock options which resulted in the issuance of 513,790 shares of common stock. For the nine months ended September 30, 2018, we received proceeds of $6.7 million upon the exercise of stock options and warrants which resulted in the issuance of 763,575 shares of common stock.

Warrants

In connection with the April 2018 amendment to the CRG Loan, we issued warrants to purchase up to 200,000 shares of our common stock with an exercise price of $23.00 per share and total fair value of $1.4 million. The warrants have a five-year term and remain outstanding as of September 30, 2019.

In September 2018, other warrant holders with a right to purchase 57,487 shares of our common stock exercised their warrants. In conjunction with this cashless exercise, we issued 34,509 shares of our common stock. As of September 30, 2019, 43,115 of these warrants remain outstanding. The warrants are exercisable through May 18, 2023.

Interim Condensed Consolidated Statements of Shareholders' Deficit

The changes in interim balances of the components of our shareholders' deficit are as follows:

	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
		(In thousands)		
Balance January 1, 2019	$ 490	$ 549,479	$ (650,125)	$ (100,156)
Exercise of stock options	—	108	—	108
Stock-based compensation expense	—	3,374	—	3,374
Net loss	—	—	(24,345)	(24,345)
Balance March 31, 2019	490	552,961	(674,470)	(121,019)
Exercise of stock options	2	1,598	—	1,600
Stock-based compensation expense	—	3,598	—	3,598
Net loss	—	—	(14,453)	(14,453)
Balance June 30, 2019	492	558,157	(688,923)	(130,274)
Exercise of stock options	3	3,323	—	3,326
Stock-based compensation expense	—	3,496	—	3,496
Net loss	—	—	(16,463)	(16,463)
Balance September 30, 2019	$ 495	$ 564,976	$ (705,386)	$ (139,915)

	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
		(In thousands)		
Balance January 1, 2018	$ 482	$ 520,072	$ (523,368)	$ (2,814)
Exercise of stock options	1	686	—	687
Stock-based compensation expense	—	2,966	—	2,966
Net loss	—	—	(30,054)	(30,054)
Balance March 31, 2018	483	523,724	(553,422)	(29,215)
Warrants issued	—	1,424	—	1,424
Exercise of stock options	2	2,188	—	2,190
Stock-based compensation expense	—	3,000	—	3,000
Net loss	—	—	(33,697)	(33,697)
Balance June 30, 2018	485	530,336	(587,119)	(56,298)
Exercise of stock options	5	3,839	—	3,844
Stock-based compensation expense	—	2,929	—	2,929
Net loss	—	—	(39,472)	(39,472)
Balance September 30, 2018	$ 490	$ 537,104	$ (626,591)	$ (88,997)

Note 10—Stock-Based Compensation

Stock-based compensation expense includes the amortization of stock options granted to employees and non-employees and has been reported in our Condensed Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Research and development	$ 1,558	$ 1,334	$ 4,698	$ 3,720
Selling, general and administrative	1,938	1,595	5,770	5,176
Total	$ 3,496	$ 2,929	$ 10,468	$ 8,896

The fair value of each option grant to employees, directors and non-employees is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were applied to all stock option grants:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Estimated weighted-average fair value	$ 11.81	$ 16.30	$ 9.91	$ 10.22
Weighted-average assumptions:				
Expected volatility	79 %	78 %	81 %	77 %
Expected term, in years	6.1	6.1	6.0	6.0
Risk-free interest rate	2.10 %	2.77 %	2.44 %	2.66 %
Expected dividend yield	— %	— %	— %	— %

Stock option activity for all stock plans and related information 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, 2018	10,313,138	$ 11.22		
Granted	1,956,205	14.17		
Exercised	(513,790)	9.80		
Forfeited	(260,831)	16.07		
Balance at September 30, 2019	11,494,722	$ 11.67	6.25	$ 56,610
Vested and expected to vest at September 30, 2019	11,126,906	$ 11.59	6.17	$ 55,668
Exercisable at September 30, 2019	8,117,842	$ 10.68	5.20	$ 47,725

At September 30, 2019, there were 3,376,880 unvested options outstanding that will vest over a weighted-average period of 2.7 years and 5,396,836 shares were available to grant. The total estimated compensation expense yet to be recognized on outstanding options is $27.4 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q.

Overview

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

Our drug product OMIDRIA® is marketed in the United States (U.S.) for use during cataract surgery or intraocular lens replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative pain. In our pipeline we have multiple Phase 3 and Phase 2 clinical-stage development programs focused on complement-mediated disorders and substance abuse. In addition, we have a diverse group of preclinical programs, including GPR174, a novel target in immuno-oncology that modulates a new cancer immunity axis recently discovered by us. Small-molecule inhibitors of GPR174 are part of our proprietary G protein-coupled receptor (GPCR) platform through which we control 54 new GPCR drug targets and their corresponding compounds. We also exclusively possess a novel antibody-generating platform. For OMIDRIA and each of our product candidates and our programs, we have retained control of all commercial rights.

Commercial Product - OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%

OMIDRIA is approved by the 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. Outside of the U.S., we have received approval from the European Commission (EC) to market OMIDRIA in the European Economic Area (EEA) for use during cataract surgery and other intraocular lens replacement procedures for maintenance of intraoperative mydriasis (pupil dilation), prevention of intraoperative miosis and reduction of acute postoperative ocular pain.

OMIDRIA is a proprietary drug product containing two active pharmaceutical ingredients: ketorolac, an anti-inflammatory agent, and phenylephrine, a mydriatic, or pupil dilating, agent. Cataract and other lens replacement surgery involves replacement of the original lens of the eye with an artificial intraocular lens. These procedures are typically performed to replace a lens opacified by a cataract and/or to correct a refractive error. OMIDRIA is added to standard irrigation solution used during cataract and lens replacement surgery and is delivered intracamerally, or within the anterior chamber of the eye, to the site of the surgical trauma throughout the procedure. Preventing pupil constriction is essential for these procedures and, if miosis occurs, the risk of damaging structures within the eye and other complications increases, as does the operating time required to perform the procedure.

We launched OMIDRIA in the U.S. in the second quarter of 2015 and sell OMIDRIA primarily through wholesalers which, in turn, sell to ambulatory surgery centers (ASCs) and hospitals. The Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for administering the Medicare program, granted transitional pass-through reimbursement status for OMIDRIA in 2014, effective from January 1, 2015 through December 31, 2017. Pass-through status allows for separate payment (i.e., outside the packaged payment rate for the surgical procedure) under Medicare Part B. In March 2018, the Consolidated Appropriations Act of 2018 (the Appropriations Act) was signed into law. The Appropriations Act included a provision by which Congress extended pass-through reimbursement status for a small number of drugs, including OMIDRIA, used during procedures performed on Medicare Part B fee-for-service patients for an additional two years, running from October 1, 2018 until September 30, 2020.

We continue to pursue permanent separate reimbursement for OMIDRIA beyond the currently scheduled expiration of pass-through reimbursement. CMS is required under the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act to review payments under its CMS'

outpatient prospective payment system (OPPS) for opioids and evidence-based non-opioid alternatives for pain management with a goal to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives. In its 2020 OPPS proposed rule, CMS noted that non-opioid drugs that are indicated for reduction of post-operative pain may warrant separate payment if there is evidence to show that such drugs help to deter or avoid prescription opioid use and addiction and that packaged payment presents a demonstrated barrier to access for such drugs. Although Omeros provided CMS with evidence that it believes shows that OMIDRIA meets these criteria, CMS declined in its 2020 OPPS final rule to grant separate payment to OMIDRIA beyond the expiration of its current pass-through status on September 30, 2020. CMS also noted in the 2020 final rule that it will continue to analyze evidence and monitor utilization of OMIDRIA. We continue to generate evidence and intend to continue pursuing administrative and legislative avenues to secure permanent separate payment or similar reimbursement for OMIDRIA beyond September 30, 2020; however, we cannot provide assurance that these efforts will be successful. For more information regarding OMIDRIA reimbursement, see "Results of Operations" below.

We also continue to pursue expansion of reimbursement for OMIDRIA by Medicare Advantage and other third-party payers. CMS recently assigned a permanent product-specific Healthcare Common Procedure Coding System (HCPCS) J-code for OMIDRIA, which became effective October 1, 2019 and replaced the drug's former temporary HCPCS C-code. J-codes are reimbursement codes used by commercial insurance plans, Medicare, Medicare Advantage, and other government payers for drugs like OMIDRIA that are administered by a physician. Benefits of the new J-code include having one consistent billing code that can be used across all government and commercial payer plans as well as expanding coverage in state Medicaid and commercial plans that recognize J-codes, but not C-codes, for reimbursement and enabling access to the increasing number of cataract procedures performed in the physician office setting.

In July 2018, we reported that OMIDRIA had been placed on the market in the EU, on a limited basis, which maintained the ongoing validity of the European marketing authorization for OMIDRIA. Decisions about price and reimbursement for OMIDRIA are made on a country-by-country basis and may be required before marketing may occur in a particular country. At this time, we do not expect to see significant sales of OMIDRIA in any countries within the EEA or other international territories.

Clinical Development Programs

Our clinical stage development programs include:

- *MASP-2 - narsoplimab (OMS721) - Lectin Pathway Disorders* Narsoplimab, also referred to as OMS721, is our lead human monoclonal antibody targeting mannan-binding lectin-associated serine protease-2 (MASP-2), a novel pro-inflammatory protein target involved in activation of the complement system. 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. MASP-2 is the effector enzyme of the lectin pathway of the complement system, and the current development focus for narsoplimab is 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 injuries, such as kidney or central nervous system injury.

  We are conducting Phase 3 clinical programs for narsoplimab in hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA), Immunoglobulin A (IgA) nephropathy, and atypical hemolytic uremic syndrome (aHUS). In addition, we have an ongoing Phase 2 clinical trial evaluating narsoplimab in renal diseases, currently focused on patients with IgA nephropathy.

  Narsoplimab has received multiple designations from the FDA and from the EMA across the three current indications. These include:

  - HSCT-TMA: In the U.S., the 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 HSCT-TMA. The EC also granted narsoplimab a designation as an orphan medicinal product for treatment in hematopoietic stem cell transplantation.

- IgA nephropathy: In the U.S., narsoplimab has received from the FDA (1) breakthrough therapy designation for the treatment of IgA nephropathy and (2) orphan drug designation in IgA nephropathy. In Europe, narsoplimab has received from the EC designation as an orphan medicinal product for the treatment of primary IgA nephropathy.

- aHUS: In the U.S., narsoplimab has received from the FDA (1) fast-track designation for the treatment of patients with aHUS and (2) orphan drug designation for the prevention (inhibition) of complement-mediated thrombotic microangiopathies.

In October 2019, we initiated the rolling submission to FDA of our BLA for narsoplimab for the treatment of HSCT-TMA. Rolling submission enables us to submit sections of the BLA as they are completed, which can accelerate the time to approval by allowing FDA to review completed sections of the application as they are submitted rather than waiting for the entire BLA to be submitted before beginning its review. The initial submission to FDA included all of the nonclinical (i.e., pharmacology, pharmacokinetics and toxicology) data, study reports, overview and summaries for the nonclinical sections of the BLA. Once all clinical data collection, dataset compilation and data analysis are complete, the clinical parts of the BLA will be scheduled for submission, to be followed by the quality (i.e., chemistry, manufacturing and controls) section.

Based on communications with the FDA and the EMA regarding expectations for our marketing applications (BLA and MAA), we plan to submit for regulatory approval of narsoplimab for HSCT-TMA with data from patients already enrolled in the ongoing HSCT-TMA clinical trial and from HSCT-TMA patients treated with narsoplimab under compassionate use protocols. We have also agreed with the FDA on the primary endpoint criteria to be used for approval. The response-based primary endpoint for HSCT-TMA requires a showing of both a beneficial effect on the underlying HSCT-TMA disease process and a meaningful improvement in patients' clinical status. The endpoint includes laboratory measures and markers of organ function as well as platelet and red blood cell transfusion burden. We are collecting the additional data needed for our marketing applications from the medical records of patients already treated with narsoplimab in our HSCT-TMA clinical trial or under a compassionate use protocol.

In Europe, EMA has confirmed narsoplimab's eligibility for EMA's centralized review procedure, which allows submission of a single MAA that, if approved, authorizes the product to be marketed in all EU member states and EEA countries rather than requiring separate national approvals. We intend to harmonize the contents of the BLA and MAA. In October 2019 we received a positive opinion from EMA on our pediatric investigation plan (PIP) for narsoplimab in the treatment HSCT-TMA. A PIP outlining a development program for the investigational product in the pediatric population must be agreed with EMA as a prerequisite to EMA's acceptance of an MAA. The narsoplimab PIP provides a study plan to evaluate the safety and effectiveness of the drug for HSCT-TMA in patients from one month through 17 years of age. We received a deferral for completion of our PIP until after approval of the narsoplimab MAA.

In our IgA nephropathy program, patient enrollment continues in the narsoplimab Phase 3 clinical trial, ARTEMIS-IGAN. The single Phase 3 trial design is a randomized, double-blind, placebo-controlled multicenter trial in patients at least 18 years of age with biopsy-confirmed IgA nephropathy and with 24-hour urine protein excretion greater than one gram per day at baseline on optimized renin-angiotensin system (RAS) blockade. This trial includes a run-in period. Initially, patients are expected to receive an IV dose of study drug each week for 12 weeks; additional weekly dosing can be administered to achieve optimal response. The primary endpoint, which we believe could suffice for full or accelerated approval depending on the effect size, is reduction in proteinuria at 36 weeks after the start of dosing. The trial is designed to allow intra-trial adjustment in sample size. For the purposes of safety and efficacy assessments, the initial sample size for the proteinuria endpoint is estimated at 140 patients in each of the treatment and placebo groups. This will include a subset of patients with high levels of proteinuria (i.e., equal to or greater than 2 g/day) at baseline, and a substantial improvement at 36 weeks in this subset of patients alone could potentially form the basis for

approval. We believe that the trial design will allow assessment for either full or accelerated approval at 36 weeks based on proteinuria results either (1) across the general population of study patients or (2) in the high-proteinuria subset of patients.

The Phase 3 clinical program in patients with aHUS, in which patient enrollment is ongoing, consists of one Phase 3 clinical trial – a single-arm (*i.e.*, no control arm), open-label trial in patients with newly diagnosed or ongoing aHUS. This trial is targeting approximately 40 patients for full approval in Europe and accelerated approval in the U.S. with approximately 80 total patients required by FDA for full approval in the U.S.

- *PDE7 - OMS527*. In our phosphodiesterase 7 (PDE7) program, we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders. In September 2019 we reported positive results from our Phase 1 single-ascending- and multiple-ascending-dose clinical trial designed to assess safety, tolerability and pharmacokinetics of our lead compound in healthy subjects.

  In the double blind, randomized Phase 1 study, the study drug, referred to as OMS182399, met the primary endpoints of safety and tolerability and showed a favorable and dose-proportional pharmacokinetic (PK) profile supporting once-daily dosing. There was no apparent food effect on plasma exposure to OMS182399.

  In the single-ascending-dose part of the study (Part 1), 47 fasted subjects received single oral doses of placebo or OMS182399 in five sequential ascending-dose cohorts and in a single-dose cohort of non-fasting (i.e., fed) subjects. In the multiple-dose part of the study (Part 2), 37 non-fasting subjects received oral doses of placebo or OMS182399 once a day for 14 days in three sequential cohorts. In aggregate, the number of subjects reporting any treatment-emergent adverse event (TEAE) was 5 of 21 (23.8 percent) for those receiving placebo and 18 of 63 (28.6 percent) for those receiving OMS182399. All TEAEs in subjects receiving OMS182399 were mild in intensity and transient. The most common TEAE in subjects receiving OMS182399 (and more frequent than placebo) was headache, occurring in 3 of 35 (8.6 percent) subjects receiving single doses and 4 of 28 (14.3 percent) subjects receiving multiple doses. No serious TEAE or lab-related TEAE was reported, and there was no dose dependency of TEAEs observed. We plan to conduct a Phase 2a study targeting nicotine addiction.

Preclinical Development Programs and Platforms

Our preclinical programs and platforms include:

- *MASP-3 - OMS906 - Alternative Pathway Disorders*. As part of our complement target program, we have identified mannan-binding lectin-associated serine protease-3 (MASP-3), which has been shown to be the key activator of the complement system's alternative pathway (APC). 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 factor D, and converted factor D is necessary for the activation of the APC. Based on our alternative pathway-related discoveries, we have expanded our intellectual property position to protect our inventions stemming from these discoveries beyond MASP-2-associated inhibition of the lectin pathway to include inhibition of the alternative pathway. Our current primary focus in this program is developing MASP-3 inhibitors for the treatment of disorders related to the APC. We believe that MASP-3 inhibitors have the potential to treat patients suffering from a wide range of diseases and conditions, including: paroxysmal nocturnal hemoglobinuria (PNH); C3 glomerulopathy; multiple sclerosis; arthritis; traumatic brain injury; neuromyelitis optica; pauci-immune necrotizing crescentic glomerulonephritis; disseminated intravascular coagulation; age-related macular degeneration; asthma; dense deposit disease; Bechet's disease; aspiration pneumonia; TMA; ischemia-reperfusion injury; Guillain Barre syndrome; Alzheimer's disease; amylotrophic lateral sclerosis; systemic lupus erythematosus; diabetic retinopathy; uveitis; chronic obstructive pulmonary disease; transplant rejection; acute respiratory distress syndrome; antineutrophil cytoplasmic antibody-associated vasculitis; anti-phospholipid syndrome; atherosclerosis; myasthenia gravis and others. Our OMS906 program has generated positive data in a well-established animal model associated with PNH. The program has also generated positive data in a well-established animal model of arthritis. In preparation for

clinical trials, the manufacturing scale-up process is underway for a MASP-3 inhibitor antibody. The initial clinical focus in this program is PNH. Nonclinical human-dose-enabling studies are planned for this year and clinical trials are targeted to begin in the first half of 2020.

- *Other MASP Inhibitor Preclinical Programs*. We have generated positive preclinical data from MASP-2 inhibition in *in vivo* models of age-related macular degeneration, myocardial infarction, diabetic neuropathy, stroke, ischemia-reperfusion injury, and other diseases and disorders. As part of lifecycle planning for narsoplimab we are developing small-molecule inhibitors of MASP-2 designed for oral administration, as well as a long-acting second-generation antibody against MASP-2 designed for subcutaneous administration. Both of these development programs are targeted for clinical entry in 2021. Development efforts to small-molecule inhibitors of MASP-3 and bispecific inhibitors of MASP-2/-3.

- *GPCR Platform and Programs*. We have developed a proprietary cellular redistribution assay which we use in a high-throughput manner to identify synthetic ligands, including antagonists, agonists and inverse agonists, that bind to and affect the function of orphan GPCRs. We are conducting *in vitro* and *in vivo* preclinical efficacy studies and optimizing compounds for a number of targets. One of our priorities in this program is GPR174. In *ex vivo* human studies, our small-molecule inhibitors targeting GPR174 upregulate the production of cytokines (e.g., IL-2, interferon-γ), block multiple checkpoints (e.g., PDL-1, CTLA-4, LAG-3) and tumor promoters (e.g., amphiregulin), and suppress regulatory T-cells. Based on our data, we believe that GPR174 controls a major pathway in cancer and modulation of the receptor could provide a seminal advance in immuno-oncologic treatments for a wide range of tumors. Our recent discoveries suggest a new approach to cancer immunotherapy that targets inhibition of GPR174 and can be combined with and significantly improve the tumor-killing effects of adenosine pathway inhibitors. These discoveries include (i) identification of cancer-immunity pathways controlled by GPR174, (ii) the identification of phosphatidylserine as a natural ligand for GPR174, (iii) a collection of novel small-molecule inhibitors of GPR174 and (iv) a synergistic enhancement of "tumor-fighting" cytokine production by T cells following the combined inhibition of both GPR174 and the adenosine pathway (e.g., A2A and/or A2B), another key metabolic pathway that regulates tumor immunity. We continue to focus on GPR174 and several other of our GPCR targets with the objective of moving compounds targeting them into human trials.

Financial Summary

For the three months ended September 30, 2019 and 2018, we recognized net losses of $16.5 million and $39.5 million, respectively, and our OMIDRIA revenues were $29.9 million and $4.6 million, respectively. During the period from January 1, 2018 to September 30, 2018, OMIDRIA was not reimbursed separately when used for procedures involving patients covered by Medicare Part B. Separate reimbursement payment for OMIDRIA was restored for a two-year period effective October 1, 2018 as a result of securing an extension of pass-through reimbursement status. In its 2020 OPPS final rule, issued on November 1, 2019, CMS declined to grant separate payment to OMIDRIA beyond the expiration of its current pass-through status on September 30, 2020. CMS also noted in the 2020 final rule that it would continue to analyze evidence and monitor utilization of OMIDRIA. See "Commercial Product - OMIDRIA" earlier in this section for additional details regarding the pass-through reimbursement status for OMIDRIA.

* Fiscal quarters without pass-through reimbursement.

We expect our net losses will continue until we derive sufficient revenues from sales of OMIDRIA and/or other sources, such as licensing, product sales and other revenues from our product candidates, that are sufficient to cover our operating expenses and debt service obligations.

As of September 30, 2019, we had $27.3 million in cash and cash equivalents and short-term investments available for general corporate use and $29.9 million in accounts receivable, net.

Results of Operations

Revenue

Our revenue consists of OMIDRIA product sales to ASCs and hospitals in the U.S. Our product sales, net are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Product sales, net	$ 29,856	$ 4,608	$ 78,389	$ 7,852

During the three and nine months ended September 30, 2019, OMIDRIA revenue was $29.9 million and $78.4 million, respectively, as compared to $4.6 million and $7.9 million for the three and nine months ended September 30, 2018, respectively. The increase in revenue during the three and nine months ended September 30, 2019 compared to the same period in prior year was due to significantly increased demand for OMIDRIA by ASCs and hospitals following the reinstatement of transitional pass-through reimbursement status for OMIDRIA on October 1, 2018. As compared to the second quarter of 2019, OMIDRIA revenue for the third quarter of 2019 increased $3.1 million, or 11.6%, from $26.8 million due to increased demand for OMIDRIA.

We anticipate that OMIDRIA product sales, net, will continue to increase in the fourth quarter of 2019; however, we are unable to predict with precision the magnitude of those increases at the current time due to the uncertainty regarding the extent to which the November 1, 2019 issuance by CMS of the OPPS final rule for 2020 and/or the recently effective product specific J-code for OMIDRIA may impact sales. See “Commercial Product - OMIDRIA” earlier in this section for additional details regarding the pass-through reimbursement status for OMIDRIA.

Gross-to-Net Deductions

We record OMIDRIA product sales net of estimated chargebacks, rebates, distribution fees and product returns. These deductions are generally referred to as gross-to-net deductions. Our total gross-to-net provision for the three and nine months ended September 30, 2019 was 28.5% and 28.0% of gross OMIDRIA product sales, respectively. This compares to 28.7% and 27.2% for the three and nine months ended September 30, 2018, respectively. The primary reason for changes in gross-to-net deductions as a percentage of sales is due to changes in chargeback and rebates under our volume-purchase discount program. We expect our gross-to net deductions will increase slightly in the fourth quarter.

A summary of our gross-to-net related accruals for the nine months ended September 30, 2019 is as follows:

	Chargebacks and Rebates	Distribution Fees and Product Return Allowances	Total
		(In thousands)	
Balance as of December 31, 2018	$ 7,015	$ 1,485	$ 8,500
Provisions	26,660	3,709	30,369
Payments	(24,585)	(3,121)	(27,706)
Balance as of September 30, 2019	$ 9,090	$ 2,073	$ 11,163

Chargebacks and Rebates

We record a provision for estimated chargebacks and rebates at the time we recognize OMIDRIA product sales revenue and reduce the accrual when payments are made or credits are granted. Our chargebacks are related to a pharmaceutical pricing agreement, a Federal supply schedule agreement, a 340B prime vendor agreement, a Medicaid drug rebate agreement and beginning in April 2019, an off-invoice discount to our ASC and hospital customers. We also record a provision for estimated rebates for our OMIDRIAssure® patient assistance and reimbursement services program and our rebates under our purchase volume-discount programs.

Distribution Fees and Product Return Allowances

We pay our wholesalers a distribution fee for services they perform for us based on the dollar value of their purchases of OMIDRIA. We record a provision for these charges as a reduction to revenue at the time of sale to the wholesaler and make payments to our wholesalers based on contractual terms.

We allow for the return of product up to 12 months past its expiration date, or for product that is damaged or not used by our customers. We record a provision for returns upon sale of OMIDRIA to our wholesaler. When a return or claim is received, we issue a credit memo to the wholesaler against its outstanding receivable to us or we reimburse the customer.

Research and Development Expenses

Our research and development expenses can be divided into three categories: direct external expenses, which include clinical research and development, preclinical research and development activities and manufacturing scale-up costs; 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, contract research organizations, clinical trial sites, collaborators, consultants, and lab supplies. Costs are reported in preclinical research and development until the program enters the clinic. Internal, overhead and other expenses consist of personnel costs, overhead costs such as rent, utilities and depreciation and other miscellaneous costs. We do not generally allocate our internal resources, employees and infrastructure to any individual research project because we deploy them across multiple clinical and preclinical projects that we are advancing in parallel.

The following table illustrates our expenses associated with these activities:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Direct external expenses:				
Clinical research and development:				
MASP-2 Program - OMS721 (narsoplimab)	$ 9,120	$ 15,660	$ 28,615	$ 31,904
OMIDRIA - Ophthalmology	657	511	1,744	1,795
PDE7 - OMS527	1,425	1,206	3,019	1,206
Other clinical programs	372	253	891	915
Total clinical research and development	11,574	17,630	34,269	35,820
Preclinical research and development	3,253	1,203	5,936	5,640
Total direct external expenses	14,827	18,833	40,205	41,460
Internal, overhead and other expenses	7,361	6,695	24,205	19,234
Stock-based compensation expense	1,558	1,334	4,698	3,720
Total research and development expenses	$ 23,746	$ 26,862	$ 69,108	$ 64,414

Direct external expenses decreased for the three and nine months ended September 30, 2019, compared to the same periods in 2018, respectively. These decreases are due primarily to the timing of third-party manufacturing scale up costs of narsoplimab including development batches produced in 2018. Clinical costs associated with the initiation of a Phase 1 clinical trial for OMS527, our PDE7 program for addiction and compulsive disorders, are included herein beginning in July 2018. The increase in direct external expenses related to our preclinical research and development expense for the three and nine months ended September 30, 2019 compared to the same periods in 2018 reflects the increase in third-party manufacturing scale up costs related to our OMS906 program offset by the advancement of OMS527 into clinical research and development in July 2018.

The increases in internal, overhead and other expenses for the three and nine months ended September 30, 2019 compared to the prior year periods are primarily due to additional employee-related costs to support our increased research and development activities.

The increase in stock-based compensation expense for the three and nine months ended September 30, 2019 compared to the prior year periods is due primarily to increases in the number of shares granted as our research and development staff has grown, as well as the Black-Scholes value per share being greater for annual performance grants made in 2019 compared to prior years.

A large majority of our research and development expenses for the fourth quarter of 2019 will be related to our narsoplimab program. We expect research and development costs to increase in the fourth quarter of 2019 as we incur incremental manufacturing scale-up costs in preparation for the planned submission of marketing applications for narsoplimab in HSCT-TMA and the potential commercialization of narsoplimab in HSCT-TMA in the U.S. and 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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Selling, general and administrative expenses, excluding stock-based compensation expense	$ 14,995	$ 11,557	$ 42,723	$ 31,654
Stock-based compensation expense	1,938	1,595	5,770	5,176
Total selling, general and administrative expenses	$ 16,933	$ 13,152	$ 48,493	$ 36,830

The increase in selling, general and administrative expenses during the three and nine months ended September 30, 2019 compared to the same periods in 2018 was primarily due to increased pre-commercialization activities for narsoplimab, sales and marketing costs related to the re-introduction of OMIDRIA in October 2018, consulting and professional service fees, and employee-related costs.

The increase in stock-based compensation expense for the three and nine months ended September 30, 2019 compared to the prior year periods is due primarily to increases in the number of shares granted as our selling, general and administrative staff has grown, as well as the Black-Scholes value per share being greater for annual performance grants made in 2019 compared to prior years.

We expect that our selling, general and administrative expenses will increase slightly in the fourth quarter of 2019 compared to current levels, primarily due to increased pre-commercialization activities for narsoplimab.

Interest Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(In thousands)		(In thousands)	
Interest expense	$ 5,715	$ 4,602	$ 16,846	$ 11,104

The increase in interest expense during the three and nine months ended September 30, 2019 compared to the same periods in the prior year was primarily due to the issuance, in November 2018, of $210.0 million aggregate principal amount of our 6.25% Convertible Senior Notes due 2023 (the Convertible Notes) which replaced $125.0 million of previously outstanding notes payable. Non-cash interest expense for the three and nine months ended September 30, 2019 was $2.4 million and $6.8 million, respectively. For more information regarding our Convertible Notes, see Part II, Item 8, “Note 8 — Convertible Senior Notes” in our Annual Report on Form 10-K for the year ended December 31, 2018.

Financial Condition - Liquidity and Capital Resources

For the nine months ended September 30, 2019, we generated net losses of $55.3 million and incurred negative cash flows from operations of $37.1 million. As of September 30, 2019, we had $27.3 million in cash, cash equivalents and short-term investments available for general corporate use that are held principally in money-market accounts. Our accounts receivable balance at September 30, 2019 was $29.9 million and we had $46.8 million of current liabilities. Additionally, we have a Loan and Security Agreement (Loan Agreement), which provides for a $50.0 million revolving line of credit facility which allows us to draw, on a revolving basis, up to the lesser of $50.0 million and 85% of our eligible accounts receivable, less certain reserves. See Part I, Item I, Note 5 – “Debt” for more information regarding the Loan Agreement.

As described earlier in this section under "Commercial Product — OMIDRIA", pass-through status for OMIDRIA allows for separate reimbursement payment (*i.e.,* outside the packaged procedural payment) to ASCs and hospitals using OMIDRIA in procedures involving patients covered by Medicare Part B. OMIDRIA has been granted pass-through reimbursement through September 30, 2020. In its 2020 OPPS final rule, issued on November 1, 2019, CMS declined to grant separate payment to OMIDRIA beyond the expiration of its current pass-through status on September 30, 2020. CMS also noted in the 2020 final rule that it would continue to analyze evidence and monitor utilization of OMIDRIA.

We continue to advance a series of clinical and preclinical programs (including three programs currently in Phase 3).While we believe that OMIDRIA will obtain permanent separate payment beyond the scheduled expiration of pass-through reimbursement on September 30, 2020, we cannot at this time predict with precision future OMIDRIA revenues due to the uncertain impact of the 2020 OPPS final rule on sales of OMIDRIA in 2019 and 2020. As a result, despite our record OMIDRIA sales over consecutive quarters, meaningful growth in OMIDRIA sales in the fourth quarter 2019 and 2020 are not included in the determination regarding our prospects as a going concern. Similarly, we are unable to include in the determination amounts available under our revolving line of credit or any proceeds from debt transactions or other financing instruments despite our successful track record in accessing capital through these avenues. We also have not included any potential partnerships related to our products or product candidates. The conditions described above, when evaluated within the constraints of the accounting literature, raise substantial doubt with respect to our ability to meet our obligations through November 12, 2020 and, therefore, to continue as a going concern.

We plan to continue to fund a portion of our operations through proceeds from sales of OMIDRIA. Should it be necessary or determined to be strategically advantageous, we also could pursue debt financings, public and private offerings of our equity securities similar to those we have completed previously, and/or other strategic transactions, which may include licensing a portion of our existing technology. If these capital sources, for any reason, are needed but inaccessible, it would have a significantly negative effect on our financial condition. Should it be necessary to manage our operating expenses, we would reduce our projected cash requirements through reduction of our expenses by delaying clinical trials, reducing selected research and development efforts, and/or implementing other restructuring activities.

Cash Flow Data

	Nine Months Ended September 30,	
	2019	2018
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	$ (37,059)	$ (79,080)
Investing activities	$ 35,838	$ 27,512
Financing activities	$ 4,221	$ 50,961

Operating Activities. Net cash used in operating activities for the nine months ended September 30, 2019 decreased by $42.0 million as compared to the same period in 2018. The net decrease in cash used in operating activities in the current period compared to the prior year is due to a $48.0 million decrease in our net loss due to significantly increased sales following the reinstatement of pass-through reimbursement for OMIDRIA effective October 1, 2018, a $9.1 million increase in funds provided by increased accounts payable and accrued expense, and a $3.6 million increase in funds provided through a decrease in advance payments. These improvements to our cash used in operating activities were partially offset by a $22.0 million increase in funds used for accounts receivable due to increased OMIDRIA sales, and a $1.3 million increase in funds used to acquire OMIDRIA inventory.

Investing Activities. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and proceeds from the sale of short-term investments, thus causing a shift between our cash and cash equivalents and short-term investment balances. Because we manage our cash usage with respect to our total cash, cash equivalents and short-term investments, we do not consider fluctuations in cash flows from investing activities to be important to the understanding of our liquidity and capital resources.

Net cash provided by investing activities during the nine months ended September 30, 2019 was $35.8 million, an increase of approximately $8.3 million from the $27.5 million net cash used in investing activities for the same period in 2018. During the nine months ended September 30, 2019 compared to the same period in 2018, the net change in our investments sold compared to purchased decreased by $36.8 million. These net proceeds provided cash to fund our operations.

Financing Activities. Net cash provided by financing activities during the nine months ended September 30, 2019 was $4.2 million, a decrease of $46.7 million compared to the same period in 2018. The decrease in net cash provided by financing activities for the nine months ended September 30, 2019 compared to the prior year was primarily due to $44.6 million in net proceeds from borrowing under our former term loan agreement with CRG Servicing LLC in May 2018. We did not have a similar borrowing during the 2019 period.

Loan and Security Agreement. On August 2, 2019, we entered into a Loan and Security Agreement with Silicon Valley Bank (the Loan Agreement), which provides for a $50.0 million revolving line of credit facility. Under the Loan Agreement we may draw, on a revolving basis, up to the lesser of $50.0 million and 85.0% of our eligible accounts receivable, less certain reserves. The Loan Agreement is secured by all our assets excluding intellectual property and development program inventories and matures on August 2, 2022. As of September 30, 2019, we had no outstanding borrowings under the Loan Agreement and we were in compliance with all covenants. See Part I, Item 1, Note 5 – "Debt" for more information regarding the Loan Agreement.

Contractual Obligations and Commitments

Our future minimum contractual commitments and obligations were reported in our Annual Report on Form 10-K for the year ended December 31, 2018. Other than the following, our future minimum contractual obligations and commitments have not changed materially from the amounts previously reported.

Goods & Services

We have certain non-cancelable obligations under various other agreements for the acquisition of goods and services associated with the manufacturing of our product candidates that contain firm commitments. As of September 30, 2019, our aggregate firm commitments are $22.6 million.

We may also 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 amount above.

Lease Agreements

We have operating leases related to our office and laboratory space in The Omeros Building. 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 December 2023. On January 1, 2019, we adopted Topic 842. The adoption did not change our contractual obligations related to lease agreements. See Part I, Item 1, Note 7 - "Lease Liabilities" for the maturities of our lease liabilities as of September 30, 2019.

Critical Accounting Policies and Significant Judgments and Estimates

There have not been any material changes in our critical accounting policies and significant judgments and estimates as disclosed in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2018, except for the adoption ASU 2016-02, *Leases.* See Part I, Item 1, Note 1 - "Organization and Significant Accounting Policies" and Note 7 - "Lease Liabilities" in this Form 10-Q for additional information about our adoption of ASU 2016-02, *Leases.*

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet arrangements.

ITEM 3. 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. 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 September 30, 2019, we had cash, cash equivalents and short-term investments of $27.3 million. In accordance with our investment policy, we invest funds in highly liquid, investment-grade securities. These securities 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 impact 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 potential loss due to changes in interest rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of 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 September 30, 2019. 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 September 30, 2019, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. 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 Quarterly Report on Form 10-Q, we were not involved in any material legal proceedings.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of risks and uncertainties. Before making an investment decision you should carefully consider the risks described in Part I, Item 1A, “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 1, 2019. In assessing the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2018, you should also refer to the other information included therein and in this Quarterly Report on Form 10-Q. 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. 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.

There has not been a material change to the risk factors as set forth in our Annual Report on Form 10-K for the year ended December 31, 2018.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
10.1	Master Services Agreement, dated July 28, 2019, between Omeros Corporation and Lonza Biologics Tuas Pte. Ltd.*
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
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
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
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
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104.1	Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101)

*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.

SIGNATURES

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

OMEROS CORPORATION

Dated: November 12, 2019

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

Dated: November 12, 2019

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

Exhibit 10.1

MASTER

SERVICES

AGREEMENT

between

LONZA BIOLOGICS TUAS PTE LTD

and

OMEROS CORPORATION

[***] 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

THIS AGREEMENT is made on the 28th day of July 2019 (the "Effective Date")

BETWEEN

1. LONZA BIOLOGICS TUAS PTE LTD, of 35 Tuas South Ave 6, SG Singapore 637377 ("Lonza") and

2. OMEROS CORPORATION, of 201 Elliott Avenue West, Seattle, WA 98119, USA ("Omeros").

Omeros and Lonza are hereinafter also collectively referred to as the "Parties" and each individually also as a "Party".

WHEREAS

A. Omeros is the proprietor of the human IgG known as narsoplimab (OMS721), an antibody that binds to and inhibits MASP-2; and

B. Lonza and its Affiliates have the expertise in the production of monoclonal antibodies for therapeutic use;

C. Omeros wishes to contract Lonza for the Launch and commercial supply of narsoplimab and for related support Services, as described in this Agreement; and

D. Lonza is prepared to perform such Services for Omeros on the terms and conditions set out herein.

NOW IT IS AGREED AS FOLLOWS:

1. Definitions and Interpretation

The following terms shall have the following meanings unless the context requires otherwise:

"Affiliate"	means any Company, partnership or other entity which directly or indirectly Controls, is Controlled by or is under common Control with the relevant Party to this Agreement.
"Agreement"	means this agreement incorporating all Appendices and Schedules as amended or varied from time to time by written agreement of the Parties.
"Applicable Laws"	means all applicable laws, including relevant federal, state and local laws, statutes, rules, and regulations which are applicable to a Party's activities in the Territory hereunder, including, without limitation, the applicable regulations and guidelines of any Governmental Authority, Food and Drug Administration (FDA) and EMA (European Medicines Agency) and all applicable cGMP together with amendments thereto, all of the clauses required to be inserted into this Agreement as set forth in U.S. Federal Acquisition Regulations (FAR) 52.244-6 that are applicable to Lonza for Manufacturing Services at the Facility, which shall be deemed to be inserted herein, and the United States Foreign Corrupt Practices Act and the UK Bribery Act 2010.

“Approval”	means marketing approval by the FDA or the EMA, of Product manufactured at the Facility for commercial supply and the date of first Approval shall be the date on which the earliest of these approvals occurs (hereinafter “First Approval"), but excludes any authorizations for limited distribution, use or sale of Product on an early access, expanded access or compassionate use basis in advance of authorization to broadly market the Product.
“Batch”	means the total Product obtained from one (1) fermentation and associated purification using the Process, which fermentation and purification will be carried out in accordance with cGMP unless otherwise agreed and specified in a SOW.
“Binding Order”	has the meaning given to it in Clause 6 3.2.
“Biosimilar”	means [***].
“Campaign”	means a series of cGMP Batches at the Facility.
"Cell Line"	means the Omeros Cell Line used by Lonza to express Product specified in Specifications Document, and any clones or derivatives thereof. For the purposes of this Agreement, "Omeros Cell Line" means a cell line provided by Omeros and any clones or derivatives thereof, used by Lonza to express Product specified in the Specifications Document.
“Certificate of Analysis”	means a document prepared by Lonza listing and certifying the tests performed by Lonza or approved external laboratories, the Specifications and test results.
“Certificate of Compliance”	means a document prepared by Lonza: (i) listing the manufacturing date, unique Batch number, and concentration of Product in such Batch, (ii) certifying that such Batch was manufactured in accordance with the Master Batch Record and, unless otherwise specified in a SOW for development work, cGMP.
“cGMP”	means those laws and regulations applicable in the U.S. and Europe, relating to the manufacture of medicinal products for human use, including, without limitation, current good manufacturing practices as specified in the ICH guidelines, including without limitation, ICH Q7A “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients”, US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC, 2003/94/EC, as amended, and 2001/83/EC, as amended. For the avoidance of doubt, Lonza’s operational quality standards are defined in internal cGMP policy documents as will be further detailed in the Quality Agreement (as such term is defined in Clause 2.14 herein).

"cGMP Product"	means Product that is required under this Agreement or a SOW to be manufactured in accordance with cGMP; for purposes of clarity, all Product manufactured under this Agreement or a SOW shall be manufactured under cGMP unless expressly agreed otherwise in a SOW for development work.
"Commencement Date"	means the date of removal of the vial of cells from frozen storage for the production of a Batch.
"Competing Contract Manufacturer"	shall mean any Third Party who, together with its Affiliates, undertakes or performs more than fifty per cent (50%) of their business as a Third Party manufacturer of monoclonal antibodies and/or therapeutic proteins or any product of a similar nature to which this Agreement relates.
"Control"	means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the Party in question.
"Development Agreement"	means the Master Services Agreement between the Parties dated 1 October 2015 and as subsequently amended, inclusive of the Reservation Letter dated 11 August 2017.
"Deliver", "Delivered" or "Delivery"	has the meaning given to it in Clause 5.
"Extension Term"	has the meaning given to it in Clause 12.1.1.
"External Laboratories"	means any Third Party instructed by Lonza, only with Omeros' advance written consent, to conduct activities required to complete the Services, including but not limited to, third parties that synthesise DNA or perform tests on the Cell Line, Product or materials derived therefrom.
"Facility"	means Lonza's manufacturing facilities in [***], or such other Lonza facility as may be mutually agreed upon in writing.
"Failure Notice"	has the meaning given to it in Clause 5.9.
"Forecast"	has the meaning given in to it in Clause 6.2.1.
"Latent Defect"	means a defect which may be present at Delivery but which cannot be detected at the time of inspection as specified in Clause 5.9 despite diligent inspection by Omeros and which is directly attributable to a breach of Lonza's obligations under this Agreement. Latent Defect shall exclude any failures due to mishandling, improper storage or contamination of the Product by Omeros or Third Parties after Delivery by Lonza.
"Launch"	means and shall be deemed to occur at such time that (i) the First Approval has been obtained and (ii) the Product has been shipped for commercial sale by or on behalf of Omeros to a wholesaler or hospital. Omeros shall provide notice of such shipment to a wholesaler or hospital in writing to Lonza (such notice not to be unreasonably delayed). For the avoidance of doubt, Launch excludes any shipment or sale of Product pursuant to authorizations

	for use, distribution or sale of Product on an early access, expanded access or compassionate use basis.
“Intellectual Property”	means all patents, copyright, rights in designs, know-how, trade secrets, and all other intellectual or industrial property rights, in each case whether registered or unregistered and including applications or rights to apply for them and together with all extensions and renewals of them, and in each and every case all rights or forms of protection having equivalent or similar effect anywhere in the world.
“Initial Term”	has the meaning given to it in Clause 12.1.
“IP-Respecting Entity”	means[***].
"Lonza Know-How"	means all technical and other information relating directly or indirectly, to the Process and/or the performance of the Services known to Lonza from time to time other than Omeros Information and information in the public domain.
"Lonza Patent Rights"	means all inventions, patents and patent applications of any kind throughout the world relating to the Process which from time to time Lonza is the owner of or is entitled to use, which for purposes of clarity shall not include inventions, patents and patent applications related to the Process to the extent specific to the Product and not generally applicable to other products.
“Master Batch Record”	means the document, proposed by Lonza and approved by Omeros, which defines the manufacturing methods, test methods and other procedures, directions and controls associated with the manufacture and testing of Product.
“Minimum Campaign”	has the meaning given to it in Clause 6 1.1.
“Minimum Exclusivity”	has the meaning given to it in Clause 4.5.
“Minimum Order”	has the meaning given to it in Clause 6 1.2.
“New General Intellectual Property”	has the meaning given to it in Clause 8.2.
“New Omeros Intellectual Property”	has the meaning given to it in Clause 8.3.
"Omeros Information"	means all technical and other information that was not known to Lonza independently of Omeros and this Agreement, or that is generated by Lonza for Omeros during the performance of Services under this Agreement, relating to the Product, the Omeros Cell Line, to the extent specific to the Product, from time to time supplied by Omeros to Lonza or generated by Lonza during the term of this Agreement and excluding any Lonza Know-How, Lonza Patent Rights and New General Application Intellectual Property.
"Omeros Materials"	means the materials supplied by Omeros to Lonza (if any) and identified as such in a Specifications Document hereto or any SOW or otherwise demonstrated by substantial written evidence to have been provided by Omeros.

[***] 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

“Omeros Patent Rights”	means all inventions, patents and patent applications of any kind throughout the world relating to the Product and improvements or modifications thereof, the Omeros Cell Line and improvements or modifications thereof, the Process to the extent specific to the Product, excluding the Lonza Patent Rights, or Lonza Know-How and New General Application Intellectual Property.
"Price"	means the price specified in (i) a SOW for the Services other than Batch manufacture or (ii) a Binding Order in accordance with Schedule 1 for manufacture of Batches.
"Process"	means the production process for the manufacture of the Product from the Cell Line, including any improvements or modifications thereto from time to time. For the purposes of this Agreement, "Omeros Process" means a Process provided by Omeros for the production of the Product from the Omeros Cell Line, inclusive of adaptations of such process by Lonza to substitute animal components (e.g., amino acids) with non-animal components, and shall, to the extent applicable, be subject to Clause 8.4 below, and "Lonza Process" means a Process provided by or developed by Lonza for the production of Product from the Omeros Cell Line using inter alia Lonza-proprietary media and feeds.
"Product"	means Omeros’ proprietary narsoplimab (OMS721) antibody to MASP-2 product manufactured using the Process (including any test sample thereof), particulars of which are set out in the Specifications Document and includes all derivatives thereof.
“Proprietary Feed License”	has the meaning given to it in Clause 2.8.
“Purchase Order”	means a purchase order placed by Omeros for the production and delivery of Batches or other Services.
“Quality Agreement”	has the meaning given to it in Clause 2.12.
“Raw Materials”	means those materials procured by Lonza and including those filters and other consumables as required and used by Lonza in the production of the Product at the Facility.
“Raw Materials Fee”	means the procurement and handling fee of [***] of the acquisition cost of Raw Materials by Lonza that is charged to Omeros in addition to the cost of such Raw Materials (excluding Resins, which are not subject to a handling fee).
“Recall”	has the meaning given to it in Clause 5.13.
“Regulatory Authority(ies)”	means the FDA, EMA, European national regulatory authorities, and any other similar regulatory authorities as may be agreed upon in writing by the Parties.
“Release”	has the meaning given to it in Clause 5.1.
"Resins"	means the purification Resins, UF membranes and any other materials that are used across multiple Batches as part of the provision of 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

"Services"	means all or any part of the services performed by Lonza (including, without limitation, cell culture evaluation, purification evaluation, master, working and extended cell bank creation, Processing and sample and bulk production of the Product), particulars of which are set out in one or more SOWs.
"Specifications"	means all written requirements, standards, quality control testing and other data for Product, particulars of which are set out in Specifications Document.
“Specifications Document”	means the mutually agreed document setting out the requirements, standards, quality control testing and other parameters for the Product, as may be amended from time to time by written agreement of the Parties.
“Statement of Work” and SOW”	means a document setting out particular Services to be performed, including a description of the Services to be performed, any agreed Price and terms of payment for the Services to be performed, and any changes or additions to previously agreed Specifications, which shall be incorporated into this Agreement upon execution by authorized representatives of each Party. In the event of any conflict between the provisions of this Agreement and the provisions of any SOW, the provisions of this Agreement shall control except to the extent that specific terms are expressly indicated in a SOW as superseding terms of this Agreement.
“Supply Failure”	has the meaning given to it in Clause 6 6.1.
“Term”	has the meaning given to it in Clause 12.1.
“Termination Fee”	means the fees payable on termination in accordance with Clause 12.6.
"Terms of Payment"	means the terms of payment specified in this Agreement with respect to Purchase Orders for Batches and the terms of payment specified in a SOW for other Services. In the event of a conflict between the provisions of this Agreement and the provisions of any Purchase Order or SOW, the provisions of this Agreement shall control.
“Territory”	means [***] and any other additional territory(ies) for which Omeros provides Lonza with reasonable prior written notice and subject to Lonza’s agreement that it can support such additional territory(ies) (such agreement not to be unreasonably withheld).
“Third Party”	means any party other than Omeros, Lonza and their respective Affiliates.

References to the singular number include the plural and vice versa, references to Clauses and Schedules are references to clauses and schedules to this Agreement.

2. Provision of the Services

2.1 (a) Lonza shall itself and through its Affiliates, diligently carry out the Services as provided in this Agreement and each SOW, and shall use reasonable endeavours to perform the Services without defect and according to the estimated timelines as set forth in this Agreement and each applicable SOW or Binding Order. Lonza will, in accordance with the terms of this Agreement and the Quality Agreement, manufacture at the Facility and Release to Customer, cGMP Batches that comply with the Master Batch Record, cGMP and the Specifications, and provide a corresponding Certificate of Analysis and Certificate of Compliance for each such cGMP Batch.

2.1 (b) Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement. Lonza may subcontract or delegate any portion of the Services under this Agreement to a Third Party analytical laboratory or other Third Party only with Omeros’ advance written approval, not to be unreasonably withheld; provided, that any such subcontracted Third Party shall be subject to the same obligations and other provisions contained in this Agreement and any applicable SOW or Binding Order and Lonza shall be responsible for such

subcontracted services, unless such subcontracted Third Party has been selected by Omeros, in which case Lonza shall not be responsible for such subcontracted services.

2.2 Lonza shall manufacture cGMP Product in accordance with the Master Batch Record to meet the Specifications using the Omeros Cell Line, provided that there shall be no such obligation to meet the Specifications in respect of the [***] cGMP Batch manufactured following any material change in the Process agreed to or requested by Omeros in writing, provided, however, that in such cases Lonza shall still be required to use commercially reasonable efforts to meet the Specifications and shall still comply with all Applicable Laws and Lonza's standard operating procedures.

2.3 The quantities of Product for Delivery set out in Purchase Orders are estimates only, which quantities Lonza shall use commercially reasonable efforts to meet. Promptly following First Approval and the manufacture of the [***] cGMP Batch manufactured on or after [***] by Lonza for Omeros at each facility at which Lonza manufactures Batches for Omeros, (not including batches manufactured under the Development Agreement or other development batches), and taking into account sampling from Batches, the Parties shall mutually determine and agree in writing on target yield quantities and an acceptable range of yield for future cGMP Batches along with associated pricing adjustments.

2.4 Without prejudice to Lonza's obligations under Clauses 2.1 and 2.2, Omeros shall be entitled to cancel any unfulfilled part of the Services or to refuse to accept the Services on grounds of late performance or late delivery to the extent specified within this Agreement.

2.5 Lonza shall perform the Services in compliance with this Agreement, the applicable SOW, all Applicable Laws and Lonza's standard operating procedures applicable to the Services.

2.6 Lonza shall not use the Cell Line, the Omeros Process, Omeros Patent Rights, Omeros Materials or Omeros Information (or any part thereof) [***] for any purpose other than the performance of the Services for Omeros under this Agreement. [***].

2.7 Lonza shall:

(a) at all times use commercially reasonable efforts to keep the Cell Line, the Omeros Information and/or Omeros Materials secure and safe from loss and damage in a commercially reasonable manner that is as rigorous as such manner as Lonza stores its own material of similar nature;

(b) not part with possession of the Cell Line and/or Omeros Materials or the Product or the Omeros Information, save for the purpose of activities at the authorized External Laboratories or as otherwise authorised in writing by Omeros; and

(c) ensure that all External Laboratories are subject to obligations of confidence substantially in the form of those obligations of confidence imposed on Lonza under this Agreement.

2.8 Omeros acknowledges and agrees that this Agreement is entered into so that Lonza can provide the Services based on the options provided below:

(a) *Omeros Cell Line and Lonza Process.*

Lonza shall provide notice to Omeros, and obtain Omeros' consent, prior to the incorporation into the Product or the Process of a material or process that would require a license from Lonza or a Third Party, which notice shall include the proposed license terms for such new material or process applicable to technology transfer in accordance with Clause 12.8 but which, in the case of any new material or process that requires a license from Lonza rather than a Third Party, such license shall be royalty free for the Process during the Term of this Agreement, but Omeros acknowledges that the terms of any license with any such Third Party shall be subject to terms and price to be agreed between Omeros and such Third Party.. If Omeros consents to such terms, the material or process may be incorporated into the Product or the Process; if Omeros does not consent to such terms, Lonza shall continue to manufacture the Product using the Process without such incorporation. Omeros shall have the option to purchase Lonza's proprietary media and feeds from Lonza or a Third Party supplier. Lonza agrees that it shall make available to Omeros a license for purchase of Lonza's proprietary feeds from Third Party suppliers or Lonza and to use the Lonza Process in connection with nonclinical and in vivo human clinical research and development, manufacture, marketing and sales and commercialization purposes (a "Proprietary Feed License"). For current and any future media and feeds, the Proprietary Feed License shall be fully paid up and subject always to Clause 12.8, no royalties or other compensation owed other than as may be charged by Third Party media and feed suppliers for supply of such current media and feeds. The Proprietary Feed License for any future media and feeds incorporated into the Process after approval by Omeros will be provided on these same terms to the extent that Lonza is able to so provide such terms. The option to purchase proprietary feeds and the Proprietary Feed License shall be assignable by Omeros to a Third Party which is an IP-Respecting Entity.

(b) *Omeros Cell Line and Omeros Process.*

Where the Cell Line is the Omeros Cell Line and Product is produced using the Omeros Process, Lonza acknowledges that, other than as conveyed to Omeros under Clause 8.4 herein, no license shall be required from Lonza for Omeros to exploit the Omeros Cell Line, the Omeros Process or the Product provided that no New General Application Intellectual Property has been applied by Lonza in the Omeros Process other than as provided under Clause 8.4 herein. Subject to the foregoing provision, Omeros shall also have the option to purchase Lonza's proprietary media and feeds from Lonza or a Third Party supplier and use such media and feeds to modify the Omeros Process. Omeros shall have the right to require a technology transfer in accordance with Clause 12.8. The option to purchase proprietary feeds and the Proprietary Feed License shall be assignable by Omeros to a Third Party which is an IP-Respecting Entity.

2.9 Unless otherwise agreed by the parties in writing or specified in the applicable SOW, Lonza shall provide all supplies (other than the materials as provided for in any SOW) and standard processing and manufacturing equipment needed for completion of the Services, at its sole cost and expense unless otherwise provided for in a SOW (including, without limitation, shipping costs in connection with such supplies and equipment). All Omeros-specific supplies and Omeros-dedicated equipment shall be specified in the SOW and shall be purchased at Omeros' reasonable cost and expense.

2.10 At Lonza's expense, Lonza shall be responsible for destruction of any and all waste, including hazardous waste, including, without limitation, rejected Product, in accordance with the Applicable Laws. Provided, however, the destruction by Lonza of any Resins owned by Omeros shall be at Omeros' request and expense.

2.11 Lonza shall, at its own cost and expense, with a reputable and solvent insurance provider, obtain and maintain in full force and effect the following insurance during the Term: (a) commercial general liability insurance with a per-claim limit of not less than [***] USD; and (b) products and completed operations liability insurance with a per-occurrence limit of not less than [***] USD and an annual aggregate limit of not less than (i) [***] USD prior to Launch and (ii) not less than [***] USD after Launch. Lonza shall supply Omeros with a copy of the certificate of insurance upon reasonable request and shall not terminate or materially decrease the level of coverage of such policies during the Term of this Agreement.

2.12 The Parties shall enter into a separate quality agreement (the "Quality Agreement") to define their responsibilities in relation to the disposition of the Product. In the event of any conflict between the terms of this Agreement and the terms of the Quality Agreement, the terms of the Quality Agreement shall control in relation to the disposition of the Product and this Agreement shall control all other aspects.

2.13 Omeros shall be permitted to have, at no additional cost, one (1) employee or contracted representative at the Facility as reasonably requested by Omeros, at any time during the Process for the purpose of observing, reporting on, and consulting as to the performance of the Services. Such employee or contracted representative shall be subject to abide by confidentiality obligations as set forth herein and Lonza's customary practices and operating procedures regarding persons in plant, and such employee agrees to comply with all instructions of Lonza's employees at the Facility.

2.14 Lonza reserves the right to initiate any and all required investigational work, such as that related to out of Specification ("OOS") investigations as set out further under a separate Quality Agreement. Lonza will inform Omeros of such investigational work as soon as reasonably practicable. Lonza will seek Omeros' approval prior to beginning such investigational work if any costs would be incurred in connection with such work would be chargeable to Omeros at Lonza's standard rates.

2.15 Raw Materials. Lonza shall procure all required Raw Materials other than those raw materials that are Omeros Materials. Omeros shall be responsible for payment of Raw Materials irrevocably committed to be procured by Lonza under a Binding Order hereunder that are not (as reasonably determined by Lonza) returnable or useable for other customers.

2.16 For any regulatory support services for Approval of the Product in each Territory that Omeros requests, the cost of any such regulatory support will be paid for by Omeros in accordance with Schedule 1 to this Agreement.

3. Scale Up Within Lonza Network

In the event that the Parties agree to transfer the manufacture of Product to a larger scale at the same Facility or such alternate Lonza facility as may be mutually agreed to meet the supply requirements, then the cost of transferring the manufacture of the Product to the larger scale or from the Facility to such other Lonza facility will be agreed in good faith between the Parties by way of an amendment to this Agreement, with manufacturing at such larger scale or at such other Lonza facility to be undertaken under the terms of this Agreement, amended solely as may be necessary to address such transfer and incorporate applicable adjustments to Batch pricing.

4. Omeros Obligations

4.1 Omeros has supplied to Lonza the Omeros Information, together with full details of any known hazards relating to the Omeros Cell Line, if applicable, and/or Omeros Materials, their storage and use. Title to the Omeros Cell Line and/or Omeros Materials and/or Omeros Information supplied to Lonza is and shall remain vested in Omeros.

4.2 Omeros shall pay the Price set out in each SOW for provision of the Services other than Batch manufacture performed in accordance with this Agreement or in accordance with Schedule 1 for Batches manufactured under this Agreement, as set out in each Binding Order, together with any additional costs and expenses that fall due under this Agreement in accordance with the Terms of Payment.

4.3 Omeros hereby grants Lonza the non-exclusive right to use the Omeros Cell Line, the Omeros Materials and the Omeros Information for the sole purpose of performing the Services in accordance with this Agreement.

4.4 Omeros shall, at its own cost and expense, obtain and maintain in full force and effect products liability insurance with a reputable and solvent insurance provider with a per occurrence limit of not less than [***] USD and an annual aggregate limit of not less than (i) [***] USD prior to Launch and (ii) not less than [***] USD following Launch. Omeros shall supply Lonza with a copy of the certificate of insurance upon reasonable request and shall not terminate or materially decrease the level of cover of such policy during the Term of this Agreement.

4.5 During the Term of the Agreement, Omeros and Lonza intend Lonza to be the supplier of a minimum of [***]% of Omeros' requirements for Product sold by Omeros or its Affiliates, to customers, to distributors, or commercial partners ("Minimum Exclusivity"), as measured on [***] sales (i.e., [***]), over any [***] calendar year period following Launch. [***].

5. Delivery, Transportation of Product and Omeros Tests

5.1 Product shall be Delivered EXW (ex-works) (as defined by Incoterms 2010) Lonza's Facility which means (a) Delivery shall occur when Lonza places Product, packaged for transport in accordance with the Specifications, at the disposal of Omeros at Lonza's premises (not cleared for export and not loaded onto a carrier's vehicle) and (b) risk and title to Product shall pass to Omeros upon Delivery ("Deliver," "Delivery," or "Delivered," as appropriate); provided, however, that Lonza shall remain responsible for storage of Product in accordance with the Specifications until Product is loaded into a carrier's vehicle and shall remain liable for any damage or loss of Product due to improper storage during this time period. Subject to Clause 5.2, Lonza shall deliver to Omeros the signed Certificate of Analysis and a completed Certificate of Compliance not later than the date of Delivery ("Release"). Transportation of Product packaged in accordance with the Specifications, whether or not under any arrangements made by Lonza on behalf of Omeros, shall be made at the sole risk and expense of Omeros. Lonza shall provide such deliverables in accordance with the shipping and packaging instructions set forth in the Specifications or applicable SOW or as otherwise provided in advance by Omeros and agreed to by Lonza and shall provide all necessary supporting shipping information.

5.2 At Omeros' request and subject to the agreement of both parties, Lonza will Deliver Product in quarantine prior to delivery of the Certificate of Analysis. Such request shall be accompanied by Omeros' written acknowledgement that the Product has been Delivered without the transmittal to Omeros of a Certificate of Analysis, that accordingly the Product cannot be administered to humans until transmittal of the Certificate of Analysis, and that Omeros nevertheless accepts full risk of loss, title and ownership of the Product. The Delivery of Product in quarantine shall be subject to such testing requirements as Lonza may reasonably require, and the forty-five (45) day period referred to in Clause 5.9 shall run from the Release of Product Delivered to Omeros.

5.3 Lonza or any subcontracted Third Party that performs testing on behalf of Lonza shall perform quality control tests in accordance with the Quality Agreement and as necessary to ensure that each Batch of Product is produced in accordance with and conforms to the Specifications and all Applicable Laws, including cGMP when applicable. All quality control test results, raw data associated with these test results and copies thereof, including notebook entries, generated by or at Lonza or by or at any subcontracted Third Party analytical laboratory, shall be made available to Omeros upon written request of Omeros at Lonza's Facility to the extent that such information is specific to Lonza's Facility or such subcontracted Third Party's facility. Lonza shall provide Omeros with timely access to properly completed copies of batch records for such Batch, prepared in accordance with the Master Batch Record, Specifications and Applicable Laws, which shall accurately reflect in all material respects the processes and procedures followed by Lonza in Processing Product.

5.4 Unless otherwise agreed, Lonza shall package and label Product for Delivery in accordance with its standard operating procedures, the Master Batch Record and the Specifications. It shall be the responsibility of Omeros to inform Lonza in writing in advance of any special packaging and labelling requirements for Product. All reasonable additional costs and expenses of whatever nature to be incurred by Lonza in complying with such special requirements shall be agreed to in advance with Omeros and then charged to Omeros in addition to the Price.

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5.5 If requested in writing by Omeros, Lonza will (acting as agent for Omeros for such purpose) arrange for insurance of Product whilst held by Lonza after Delivery (awaiting transportation) for a maximum of fourteen (14) days on terms equivalent to those under which Lonza insures product prior to Delivery. All additional costs and expenses of whatever nature incurred by Lonza in arranging such insurance shall be charged to Omeros in addition to the Price.

5.6 If requested in writing by Omeros, Lonza will (acting as agent of Omeros for such purpose) arrange the transportation of Product from Lonza's premises to the destination indicated by Omeros together with insurance coverage for Product in transit at its invoiced value. All additional costs and expenses of whatever nature incurred by Lonza in arranging such transportation and insurance shall be charged to Omeros in addition to the Price.

5.7 Where Lonza has made arrangements for the transportation of Product, Omeros or its Third Party designee shall diligently examine the Product for transportation damage as soon as practicable after receipt. Notice of all claims (time being of the essence) arising out of:

(a) visible damage to or total or partial loss of Product in transit shall be given in writing to Lonza and the carrier within three (3) working days of receipt by Omeros; or

(b) non-delivery shall be given in writing to Lonza within ten (10) days after the date of Lonza's despatch notice, which despatch notice shall be e-mailed contemporaneously with shipment to an Omeros project manager designated by Omeros.

5.8 Omeros shall make damaged Product and associated packaging materials available for inspection and shall comply with the requirements of any insurance policy covering the Product notified by Lonza to Omeros. Lonza shall offer Omeros all reasonable assistance (at the cost and expense of Omeros) in pursuing any claims arising out of the transportation of Product.

5.9 Promptly following receipt of Product or any sample thereof, Omeros may carry out any of the tests outlined or referred to in the Specifications or any SOW. Subject to Clause 2.2, if such tests show that the Product fails to meet Specifications, then Omeros shall provide Lonza written notice thereof ("Failure Notice") within forty-five (45) days from the date of Release and shall, upon Lonza's request and with Omeros' agreement, return such Product to Lonza's premises for further testing (at Lonza's cost and expense if the Product is shown to fail to meet Specifications and such failure is due (in whole or in part) to the acts of omissions of Lonza). In the absence of such Failure Notice, Product shall be deemed to have been accepted by Omeros as meeting Specifications.

Subject to Clause 2.2, if a Batch fails to meet the Specification prior to Delivery, or if Omeros has reasonably demonstrated to Lonza that Product that has been Delivered fails to meet Specification and that such failure is not due (in whole or in part) to acts or omissions of Omeros or any Third Party after Delivery, Lonza shall propose to Omeros a schedule for manufacture and Delivery of a replacement for the failed Batch. Omeros may accept or reject the proposed replacement schedule of any failed Batch. If Omeros accepts the proposed replacement schedule of any failed Batch, then Lonza shall Process and Deliver the replacement Batch in accordance with the agreed replacement schedule, and following Delivery, Omeros shall pay Lonza the remaining [***] of the Batch Price (taking into account the [***] payment already made by Omeros in respect of the failed Batch), provided, however, that if the agreed scheduled thaw date for the replacement Batch is later than [***] months after the scheduled Commencement Date of the original failed Batch, Lonza shall if requested by Omeros refund the initial [***] payment already made by Omeros and reinvoice Omeros for such payment to be made upon the rescheduled Commencement Date. If Omeros rejects the proposed replacement of any failed Batch, then Lonza shall issue a credit or, if requested by Omeros, pay a refund to Omeros for the amount of the Price previously paid that relates to the production of such failed Batch. In the event that Lonza is required to replace such Product, Lonza shall use all reasonable endeavours to do so with the minimum delay having regard to its commitments to third parties in the timing of such replacement. Omeros shall notify Lonza of any Latent Defect immediately upon discovery. Lonza shall be responsible for Latent Defects which are directly attributable to Lonza's breach of obligations under this Agreement and Omeros shall have the same remedies available to it hereunder.

5.10 Subject to Clause 2.2, if there is any dispute concerning (i) whether Product fails to comply with Specifications or cGMP or (ii) whether such failure is due (in whole or in part) to acts or omissions of Omeros or any Third Party after Delivery, such dispute shall be referred for decision to an independent expert (acting as an expert and not as an arbitrator) to be appointed by agreement between Lonza and Omeros. The costs of such independent expert shall be borne equally between Lonza and Omeros. The decision of such independent expert shall be in writing and, save for manifest error on the face of the decision, shall be binding on both Lonza and Omeros.

5.11 Except as otherwise expressly set forth in this Agreement, the provisions of Clauses 2.4, 5.9 and 5.10 shall be the sole remedy available to Omeros in respect of Product that fails to meet Specification.

[***] 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

5.12 Following completion of each Batch of Product retained samples will be stored at Lonza's Facility in accordance with the Applicable Laws, the Master Batch Record and any instructions set forth in a SOW, including for the time period of any stability study to be performed in accordance with any SOW. After the expiration of any minimum hold periods required by the Applicable Laws and/or any SOW, Lonza will notify Omeros in writing if it intends to dispose of specified samples, at Omeros' reasonable cost, unless written instructions have been provided by Omeros to Lonza within thirty (30) days of Omeros' receipt of such disposal notice to return samples to Omeros or a Third Party designee at Omeros' reasonable cost. Lonza will return unused Omeros Materials to Omeros within ninety (90) days of the termination of the relevant SOW, at Omeros' reasonable cost, unless prior written instructions have been provided by Omeros to dispose of such materials at Omeros' reasonable cost. Lonza will store Omeros Materials free of charge during the term of the applicable SOW and for thirty (30) days thereafter.

5.13 If a Regulatory Authority orders or requires the recall of any Product supplied hereunder or if Omeros or Lonza believes a recall, field alert, biological product deviation, Product withdrawal or field correction ("Recall") may be necessary with respect to any Product supplied under this Agreement, the Party receiving the notice from the Regulatory Authority or that holds such belief shall promptly notify the other Party in writing. With respect to any Recall, Lonza shall provide all necessary cooperation and assistance to Omeros. The cost of any Recall shall be borne by Omeros, and Omeros shall reimburse Lonza for reasonable expenses incurred in connection with any Recall, except to the extent such Recall is caused by (A) Lonza's negligence in which case Lonza's liability for such Recall costs and reasonable expenses is the Price charged for the recalled Product or (B) Lonza's gross negligence or willful misconduct, in which case Lonza's liability for such Recall costs and expenses shall not be limited. For purposes of clarification, Recall costs and reasonable expenses shall include, without limitation, notification to customers, Product retrieval, Product destruction, recall-related regulatory submissions, shipping and taxes. In the event that a Product is Recalled or Omeros is required to disseminate information relating to Product covered by this Agreement, Omeros shall so notify Lonza within a reasonable time so as to enable Lonza to provide Omeros with such assistance in connection with such Recall as may reasonably be requested by Omeros. Lonza will comply with all such reasonable requests from Omeros. Omeros shall handle exclusively the organization and implementation of all Recalls of Products. Any such Recall shall be implemented and administered in a manner that is appropriate and reasonable under the circumstances and in conformity with any requests or orders of the applicable Regulatory Authority and, to the extent consistent, accepted trade practices.

6. Minimum Order, Forecasting, Ordering, Rescheduling, Cancellation, and Supply Failure

6.1 Minimum Order

6.1.1 *Minimum Campaign Size.* The minimum Campaign size shall be [***] Batches ("Minimum Campaign").

6.1.2 *Minimum Order*. Commencing from the [***] of the [***] following Launch, Omeros commits to order and Lonza commits to supply not less than [***] Batches per calendar year ("Minimum Order"). For purposes of illustration only, the following is an example of the calculation for commencement of the Minimum Order: If Launch occurs on [***], then Omeros' commitment to the Minimum Order begins for the calendar year commencing [***].

6.2 Forecasting for Batches

6.2.1 *Forecast*. Omeros shall provide to Lonza, in writing, a rolling [***] forecast, based on desired Delivery date, of the number of Batches to be ordered in each calendar year. The forecast shall be updated [***] by Omeros (e.g., each [***]) and is non-binding (the "Forecast").

6.2.2 *Forecast Response.* No later than [***] following Lonza's receipt of a Forecast, Lonza shall respond to each Forecast ("Forecast Response") with a written schedule to Omeros of whether it has (as of the date of receipt of the Forecast) capacity available to manufacture the number of Batches Forecasted therein, and shall provide Omeros with an estimated production schedule showing the estimated Commencement Date and Delivery date of such Batches. Lonza shall schedule all Batches for manufacture in each calendar year as [***], unless otherwise requested by Omeros in the Forecast; provided, however, that, at its option, Omeros shall have the right to split annual aggregate orders of [***] or more Batches into [***] Campaigns, each at least as large as the Minimum Campaign size. If [***] Batches during a calendar year are split into [***] Campaigns at Omeros' request, the Batch Price shall be determined based on the size of the [***] Campaigns. If [***] Batches during a calendar year are split into [***] Campaigns by Lonza and not in response to a request by Omeros, the Batch Price shall be determined based on the aggregate number of Batches ordered in the Binding Order.

6.2.3 [***].

6.3 Purchase Orders

6.3.1 Omeros shall issue a Purchase Order for any Batches it wishes to order in accordance with the Lonza Forecast Response no later than [***] prior to the Commencement Date of each Campaign.

6.3.2 Lonza shall confirm the Commencement Date(s), Delivery date(s) and number of Batches to be Delivered to Omeros as set out in each Purchase Order within [***] of receipt from Omeros of the relevant Purchase Order. Upon acceptance of each Purchase Order from Lonza, it will then be regarded by the Parties as a binding order ("Binding Order"). Any Commencement Date or Delivery date set forth in Lonza's written confirmation of a Purchase Order shall be an estimated date only, provided that the estimated Commencement Date or Delivery date for a Batch by Lonza is no earlier or no later than [***] from Lonza's most recent Forecast Response.

6.3.3 Omeros may request to add additional Batches into an existing Campaign under a Purchase Order with less than [***] prior notice and Lonza shall determine and notify Omeros within [***] of such request whether such additional Batches can be accommodated into that Campaign, creating a Binding Order if accepted by Lonza. For clarity, Lonza shall have no obligation to accept Purchase Orders for any requested additional Batches, or to reserve capacity prior to accepting such requested Purchase Orders.

6.3.4 Unless otherwise permitted by Lonza in its discretion, Omeros shall issue Purchase Orders for any Services other than Batch manufacture no later than [***] prior to the commencement of each of the Services or such earlier time as reasonably requested by Lonza.

6.3.4 Any additional or inconsistent terms or conditions of any Omeros-issued Purchase Orders, acknowledgement or similar standardized form given or received pursuant to this Agreement shall have no effect and such terms and conditions are hereby rejected, unless specifically acknowledged and accepted by Lonza.

6.4 Rescheduling

6.4.1 Lonza shall have the right to reschedule the Commencement Date and Delivery Date of any Batch or Campaign under Binding Order upon reasonable prior written notice to Omeros, delivered as soon as reasonably practicable following Lonza's determination that it wishes to reschedule a Batch or Campaign; provided, that the rescheduled Commencement Date and Delivery Date is no earlier or no later than ninety (90) days from the Commencement Date and Release Date originally estimated at the time of Lonza's confirmation of the Binding Order, and that any such Batches that are delayed by Lonza into a subsequent calendar year, shall count towards Omeros' annual total for the originally scheduled calendar year for purposes of the Minimum Campaign or Minimum Order, as applicable.

6.4.2 Omeros shall have the right to request to reschedule any Batch or Campaign upon prior written notice to Lonza. Lonza shall use commercially reasonable efforts to accommodate such reschedule request from Omeros wherever possible, but whilst observing its contractual commitments of other customers. [***] Omeros acknowledges that any such rescheduling request may not be fulfilled by Lonza.

6.5 Cancellation of a Batch under Binding Order

6.5.1 Omeros shall notify Lonza of any Batches (the Binding Order for which has been confirmed) that it wishes to cancel. Lonza shall use commercially reasonable efforts to try and secure a replacement batch for a new project, whilst observing its contractual commitments of other customers.

6.5.2 If Lonza is unable to resell the cancelled Batch(es), Omeros shall pay [***] of the Batch Price for each Batch cancelled in accordance with the previously agreed Batch Price payment schedule of [***] at scheduled Commencement Date and [***] at scheduled Release date.

6.5.3 If Lonza is able to resell any cancelled capacity to any Third Party then the cancellation fee provided for under Clause 6.5.2 for that Batch shall be waivered.

6.5.4 In addition, any Raw Materials that are irrevocably committed and shall expire before use in any other production Campaign shall be invoiced by Lonza and paid for by Omeros in accordance with the previously agreed scheduled Release date and the handling fee shall be paid for by Omeros. Such Raw Materials may be either shipped to Omeros, stored for future use for Omeros, or disposed of as requested by Omeros. All such Raw Materials paid for by Omeros shall be owned by Omeros.

6.6 Supply Failure

6.6.1 Following Launch of the Product, If Lonza fails (where failure, for example, includes but is not limited to, failure to comply with the Master Batch Record during Processing of a Batch, failure of a Batch to meet Specifications, failure to Deliver a Batch, or failure due to reasons within Lonza's control to Release a Batch) to produce [***] or more Batches within a [***] ("Supply Failure"), Lonza 's remediation plan for the Supply Failure shall be to Deliver replacement Batches within [***] (or any such timeframe as agreed between the Parties) of such Supply Failure. In the event that Lonza is unable to Deliver replacement Batches within the above timeframe, Omeros may terminate this Agreement by providing [***] advance written notice.

7. Price and Terms of Payment

7.1 Unless otherwise indicated in writing by Lonza, all prices and charges are exclusive of Value Added Tax or of any other applicable taxes, levies, imposts, duties and fees of whatever nature imposed by or under the authority of any government or public authority, which shall be paid by Omeros (other than taxes on Lonza's income). All invoices are strictly net and payment must be made within thirty (30) days of receipt of invoice unless disputed. Payment shall be made without deduction, deferment, set-off, lien or counterclaim of any nature.

7.2 Any invoices that are disputed by Omeros must be notified to Lonza in writing and within thirty (30) days of issue of the invoice by Lonza. The Parties shall meet (in person or by telephone) within ten (10) days to resolve such dispute. Payment shall be made promptly after resolution of the dispute.

7.3 In case of any default of payment on the due date:

(a) interest shall accrue on any amount overdue of an undisputed invoice at the rate of [***] percent per month, interest to accrue on a day to day basis both before and after judgment and not exceeding more than [***] percent per annum; and

(b) Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights, be entitled to suspend the provision of the Services or to treat this Agreement as repudiated on not less than thirty (30) days' prior notice in writing to Omeros given at any time thereafter unless such payment default is cured during or after such notice period and prior to repudiation.

7.4 Price Adjustments

7.4.1 Not more than once per calendar year, to be effective after March 31 of that year, Lonza may increase the Price for Batches in accordance with the US Department of Labor's Bureau of Labor Statistics Pharmaceutical Preparations Index, [***] (or any successor index) increase for the previous calendar year. Any new Price reflecting a Batch Price adjustment shall be effective only for Purchase Orders submitted in [***] and subsequent years and any Price increase shall not exceed [***% per annum]. Purchase Orders placed in a calendar year by Omeros for Delivery of Batch(es) in that same calendar year, and accepted by Lonza, shall not be subject to any Price increase.

7.4.2 In addition to the above, the Price may be changed by Lonza, upon reasonable prior written notice to Omeros (providing reasonable detail in support thereof), to reflect (i) any change in Process conditions that materially impact Lonza cost of manufacture and (ii) any material change in an environmental, safety or regulatory standard to the extent such change materially impacts manufacturing costs exclusive of capital expenditures.

7.4.3 In the event Omeros awards a second product to Lonza the parties shall enter into good faith discussions to review the annual Price adjustments of Clause 7.

7.5 Invoicing

7.5.1 Invoices will not be provided to Omeros until the related activity is initiated or completed.

7.5.2 Lonza shall issue invoices to Omeros for [***] percent of the Price for Batches upon the Commencement Date of each Batch and [***] percent upon Release of each Batch, unless otherwise stated in the SOW or under a Binding Order, provided, however, that if a Batch is rejected the final [***] payment shall not become due until an investigation is completed and then payment responsibility will depend on the outcome of the investigation. Lonza shall (a) issue invoices for Services (other than the manufacture of Batches) in accordance with the schedule set forth in the applicable SOW. Omeros shall pay all undisputed invoices within 30 days of receipt or as otherwise set forth in the SOW.

7.5.3 Charges for Raw Materials and the Raw Materials Fee for each Batch shall be invoiced upon the Release of each Batch.

7.5.4 The cost of Resins will be invoiced by Lonza to Omeros upon purchase of the Resins by Lonza.

7.5.5 Any External Laboratory testing costs associated with testing will be invoiced upon Delivery of Batch.

8. Intellectual Property

8.1 Neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Intellectual Property that the other Party owns or controls as of the Effective Date of this Agreement, or that the other Party obtains ownership or control of separate and apart from the performance of the Services under this Agreement.

8.2 Lonza shall own all right, title and interest in "New General Application Intellectual Property," which as used in this Agreement means Intellectual Property that Lonza and/or its Affiliates, contractors or agents develops, conceives, invents, reduces to practice or makes in the course of performance of the Services and that [***].

8.3 Except for and not including the New General Application Intellectual Property, Omeros shall own all right, title, and interest in (a) any and all Intellectual Property that Lonza and/or its Affiliates conceives, invents, reduces to practice, develops or makes, solely or jointly with Omeros or others, [***] and (b)[***] (collectively, the "New Omeros Intellectual Property"). Omeros grants to Lonza a non-exclusive, non-transferable, royalty-free license to use the New Omeros Intellectual Property solely to the extent necessary for Lonza to perform its obligations under this Agreement. No other license to the New Omeros Intellectual Property is hereby granted. Lonza hereby assigns to Omeros and shall continue to assign to Omeros all of its right, title and interest in any New Omeros Intellectual Property. Lonza shall promptly disclose to Omeros in writing all New Omeros Intellectual Property. Lonza shall execute, and shall require Lonza's personnel involved in the performance of the Services to execute, any documents required to confirm Omeros' ownership of the New Omeros Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Omeros Intellectual Property. Upon Omeros' request and at Omeros' reasonable expense, and at no cost to Lonza, Lonza shall assist Omeros as may be necessary to apply for, maintain and enforce any patent or other right in the New Omeros Intellectual Property. For the avoidance of doubt, the parties agree that the term "New Omeros Intellectual Property" shall not under any circumstances be interpreted or defined to include any "New General Application Intellectual Property".

8.4 [***]

9. Warranties and Indemnification

9.1 Lonza Warranty. Lonza warrants that:

(a) the Services shall be performed in accordance with Clauses 2.1, 2.2 and 2.5;

(b) unencumbered title (save for any Intellectual Property rights which may exist) to Product will be conveyed to Omeros upon Delivery;

(c) as of the date of this Agreement the Lonza Know How and Lonza Patent Rights are owned by Lonza or Lonza is otherwise entitled to use them for the purposes of providing Services under this Agreement and during the term of this Agreement Lonza shall not do or cause anything to be done that would adversely affect their ownership or entitlement to use the same for those purposes;

(d) Lonza has the necessary corporate authorisations to enter into this Agreement;

(e) as of the date of this Agreement to the best of Lonza's knowledge and belief, the use by Lonza of the Process (excluding any modifications or steps made or developed by Omeros, Omeros Materials, Omeros Information and Omeros Patent Rights), and Lonza Patent Rights and Lonza Know How for the performance of the Services as provided herein will not infringe any rights (including without limitation any intellectual or industrial property rights) vested in any Third Party;

(f) Lonza will notify Omeros in writing immediately if it receives or is notified of a claim from a Third Party that the use by Lonza of the Process and/or the Lonza Know How or the Lonza Patent Rights for Services infringes any Intellectual Property rights vested in such Third Party;

(g) subject to Clause 2.2 and at the time of Delivery by Lonza, Product shall have been Processed in accordance with Applicable Laws and in conformance with the Specifications, and shall not be adulterated, misbranded or mislabelled within the meaning of Applicable Laws or misused, contaminated, tampered with or otherwise altered or mishandled while in the custody and control of Lonza, provided, that Lonza shall not be liable for defects attributable to Omeros Materials or a breach of representations and warranties made by Omeros under this Agreement;

(h) none of Lonza's officers, directors, employees or, to Lonza's knowledge, direct subcontractors, providing Services under this Agreement, or Affiliates has been debarred or, to Lonza's knowledge, threatened with debarment under the United States Generic Drug Enforcement Act or convicted of a crime which could lead to debarment, and it has not utilized, and will not utilize, the services of any individual or entity in the performance of any SOW that has been debarred or threatened with debarment under the United States Generic Drug Enforcement Act, convicted of a crime that could lead to debarment by the FDA, and in the event that Lonza receives notice of the debarment or threatened debarment of any individual or entity utilized by Lonza in connection with the Services, Lonza shall notify Omeros in writing immediately, and Omeros shall have the right to terminate this Agreement upon written notice in accordance with Clause 12.2 of this Agreement, and make payments to Lonza of all accrued and unpaid obligations up to the date of termination without any further financial penalties;

(i) each Certificate of Analysis and Certificate of Compliance will be true and correct and accurately reflect the results of the tests conducted on the Batch of Product to which it relates, and the records Delivered to Omeros will accurately reflect in all

material respects the processes and procedures followed by Lonza in Processing Product as set forth in the SOW, Master Batch Record and Specifications; and

(j) Lonza has obtained (or will obtain prior to Processing Product or performance of other Services), and will remain in compliance with during the term of this Agreement, all permits, licenses and other authorizations which are required under Applicable Laws for the provision of the Services under this Agreement.

9.2 Omeros Warranty. Omeros warrants that:

(a) Omeros has and shall at all times throughout the term of this Agreement have the right to supply the Omeros Cell Line, the other Omeros Materials and the Omeros Information to Lonza and the necessary rights to license or permit Lonza to use the same for the purpose of the Services;

(b) Omeros has the necessary corporate authorisations to enter into this Agreement;

(c) any of the Omeros Cell Line, the other Omeros Materials, Omeros Information and Omeros Patent Rights not owned by Omeros are licensed to Omeros under a license which will permit their use by Lonza to perform the Services;

(d) to the best of Omeros' knowledge and belief, the use by Lonza of the Omeros Cell Line, other Omeros Materials, Omeros Information and Omeros Patent Rights for the Services (including without limitation the Processing of the Product) will not infringe any Intellectual Property rights of any Third Party (provided, however, that Lonza shall waive any breach of this warranty that arises if a court of competent jurisdiction determines that the use by Lonza of the Omeros Cell Line, other Omeros Materials, Omeros Information or Omeros Patent Rights for the Services infringes the Intellectual Property rights of a Third Party, provided that and for so long as Omeros actually indemnifies Lonza pursuant to Clause 9.5 below); and

(e) Omeros will promptly notify Lonza in writing if it receives or is notified of a claim from a Third Party that the Omeros Cell Line, other Omeros Materials, Omeros Information or the Omeros Patent Rights or that the use by Lonza thereof for the provision of the Services infringes any Intellectual Property rights of such Third Party.

9 . 3 Disclaimer. THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND, EXCEPT FOR THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT, ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, ARE EXPRESSLY DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

9 . 4 Indemnification by Lonza. Subject to Clauses 9.6, 9.7 and 9.8 below, Lonza shall defend, indemnify and hold harmless each of Omeros (including Affiliates) and its directors, officers, and employees and the successors and assigns of any of the foregoing (each an "Omeros Indemnitee") from and against (i) any Third Party claim, loss, damage, costs and expenses (including court costs and legal fees on a full indemnity basis) arising directly out of any breach of the warranties given by Lonza in Clause 9.1 above or (ii) any Third Party claims alleging that Lonza's use of Lonza Know-How (excluding use of Lonza Know-How with Omeros Materials or Omeros Information if such use of the Lonza Know-How would not be infringing unless used specifically with Omeros Materials or Omeros Information) infringes any rights (including without limitation any intellectual property rights) vested in a Third Party (whether or not Lonza knows or ought to have known the same) provided that there shall be excluded from this indemnity all Omeros revenue, in each case, to the extent that such claims resulted from the negligence, intentional misconduct or breach of this Agreement by the Omeros Indemnitee. Lonza shall further indemnify and maintain Omeros promptly indemnified against all Third Party claims, actions, costs, expenses (including court costs and legal fees on a full indemnity basis) or other liabilities whatsoever caused by the negligent act or omission of Lonza in the Processing and/or supply of Product.

9.5 Indemnification by Omeros. Subject to Clauses 9.6 and 9.7 below, Omeros shall defend, indemnify and hold harmless each of Lonza (including Affiliates) and its directors, officers, and employees and the successors and assigns of any of the foregoing (each a "Lonza Indemnitee") from and against (i) any Third Party claim, loss, damage, costs and expenses of any nature (including court costs and legal fees on a full indemnity basis), arising directly out of any breach of the warranties given by Omeros in Clause 9.2 above or (ii) any Third Party claims alleging Lonza's use of the Omeros Cell Line, the Omeros Materials or the Omeros Information infringes any rights (including, without limitation, any intellectual property rights) vested in any Third Party (whether or not Omeros knows or ought to have known about the same) provided that for purposes of clarity there shall be excluded from this indemnity all Lonza actual or potential revenues other than those which are an integral part of any Price or fees that Omeros is obliged to pay to Lonza under this Agreement, in each case, to the extent that such claims resulted from the negligence, intentional misconduct or breach of this Agreement by the Lonza Indemnitee. Omeros shall further indemnify and maintain Lonza promptly indemnified against all Third Party claims, actions, costs, expenses (including court costs and legal fees on a full indemnity basis) or other liabilities whatsoever in respect of:

(a) any product liability in respect of Product, unless such liability is caused by the negligent act or omission of Lonza in the Processing and/or supply of Product; and

(b) any negligent or wilful act or omission of Omeros in relation to the use, Processing, storage or sale of the Product.

9.6 Indemnification Procedure. If a Lonza Indemnitee or Omeros Indemnitee (the "Indemnitee") intends to claim indemnification under this Clause 9, it shall promptly notify the other Party (the "Indemnitor") in writing of such alleged liability. The Indemnitor shall have the right to control the defence thereof with counsel of its choice as long as such counsel is reasonably acceptable to Indemnitee; provided, however, that any Indemnitee shall have the right to retain its own counsel at its own expense, for any reason, including if representation of any Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party reasonably represented by such counsel in such proceeding and provided further that the Indemnitor may not admit to any unlawful act or infringement of a Third Party's Intellectual Property by the Indemnitee or agree to any invalidity or unenforceability of an Indemnitee's patent rights without the indemnitee's written consent. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any liability covered by this Clause 9. The obligations of this Clause 9.6 shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve the Indemnitor of any obligation to the Indemnitee under this Clause 9. It is understood that only Lonza or Omeros may claim indemnity under this Clause 9 (on its own behalf or on behalf of its Indemnitees), and other Indemnitees may not directly claim indemnity hereunder.

9.7 Disclaimer of Consequential Damages. Subject to the second sentence of this Clause 9.7, in no event shall either Party be liable to the other Party for incidental, indirect, special, punitive or consequential damages arising from or related to breach of this Agreement. The foregoing disclaimer of damages shall not apply in the case of (a) breach of Clause 10 (Confidentiality), (b) personal injury or death, or (c) grossly negligent or intentionally wrongful acts or omissions.

9.8 Limitation of Liability. Except for Lonza's indemnification obligations under Clause 9.4 and the exceptions set forth in the second sentence of Clause 9.7 and the second sentence of this Clause 9.8, in no event shall Lonza's liability to Omeros for direct damages arising from or related to breach of this Agreement exceed [***] payable under this Agreement for Services, including under any Binding Orders not yet completed, by Omeros. The foregoing limitation of liability shall not apply in the case of (a) breach of Clause 10 (Confidentiality), (b) personal injury or death, or (c) grossly negligent or intentionally wrongful acts or omissions.

10. Confidentiality

10.1 Omeros acknowledges that Lonza Know-How and Lonza acknowledges that Omeros Information with which it is supplied by the other pursuant to the Agreement, and Omeros Information that Lonza generates for Omeros during the course of performing Services under this Agreement, is supplied or generated, subject to Clause 10.5, in circumstances imparting an obligation of confidence and each agrees to keep such Lonza Know-How or such Omeros Information secret and confidential and to respect the other's proprietary rights therein and not at any time for any reason whatsoever to disclose or permit such Lonza Know-How or such Omeros Information to be disclosed to any Third Party save as expressly provided herein.

10.2 Omeros and Lonza shall each ensure that all their respective employees, consultants, contractors and persons for whom it is responsible having access to Lonza Know-How or Omeros Information shall be subject to the same obligations of confidence and non-use as the principals pursuant to Clauses 10.1 and 10.3 and shall be bound by secrecy and non-use agreements in support of such obligations, and Omeros and Lonza may share information with such employees, consultants, contractors and persons, in accordance with the foregoing obligations, on a need-to-know basis and solely for purposes of performance under this Agreement and to permit Omeros' development and full use of the Product in conformance with the terms of this Agreement.

10.3 Lonza and Omeros each undertake not to disclose or permit to be disclosed to any Third Party (including, except as provided in Clause 10.2 above, any contractors or consultants not previously approved in writing by the Parties, such approval not to be unreasonably withheld or delayed), or otherwise make use of or permit to be made use of other than for purposes of performance under this Agreement (a) any trade secrets or confidential information relating to the technology, business affairs or finances of the other, any subsidiary, holding company or subsidiary or any such holding company of the other, or of any suppliers, agents, distributors, licensees or other customers of the other which comes into its possession under this Agreement or (b) the commercial terms of this Agreement except as required to be disclosed by applicable laws or regulations; provided, however, that, except for filings required under the United States Securities Exchange Act of 1934 and applicable rules promulgated

[***] 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

thereunder, in each case to any extent that such information is required to be disclosed pursuant to subpoena, court order, judicial process or otherwise by law, provided the receiving Party provides prompt notice to the disclosing Party of such requirement in order to give the disclosing Party an opportunity to timely seek a protective order or other appropriate judicial relief. In the event the disclosing Party is unable to obtain a protective order or other appropriate judicial relief, the receiving Party shall disclose only that portion of the disclosing Party's confidential information which is legally required to be disclosed, and ensure that all such confidential information of the disclosing Party shall be redacted to the fullest extent permitted by law prior to such disclosure and that the disclosing Party shall be given an opportunity to review the confidential information prior to its disclosure.

10.4 The obligations of confidence and non-use referred to in this Clause 10 shall not extend to any information which the Party seeking to disclose such information:

(a) is or becomes generally available to the public otherwise than by reason of a breach by the receiving Party of the provisions of this Clause 10;

(b) is known to the receiving Party and is at its free disposal prior to its receipt from the disclosing Party;

(c) is subsequently disclosed to the receiving Party without being made subject to an obligation of confidence by a third Party;

(d) Lonza or Omeros may be required to disclose under any statutory, regulatory or similar legislative requirement, subject to the imposition of obligations of secrecy wherever possible in that relation; or

(e) is developed by any servant or agent of the receiving Party without access to or use or knowledge of the information by the disclosing Party.

10.5 The Parties acknowledge that:

(a) without prejudice to any other rights and remedies that the Parties may have, the Parties agree that the Lonza Know-How and Omeros Information is valuable and that damages may not be an adequate remedy for any breach of the provisions of this Clause 10. The Parties agree that the relevant Party will be entitled without proof of special damage to seek the remedies of an injunction and other equitable relief for any actual or threatened breach by the other Party;

(b) save as provided herein Lonza shall not at any time have any right, title, license or interest in or to Omeros Information, Omeros Patent Rights or any other intellectual property rights vested in Omeros or to which Omeros is entitled; and

(c) Omeros shall not at any time have any right, title, license or interest in or to Lonza Know-How, the Lonza Patent Rights or any other intellectual property rights relating to the Process which are vested in Lonza or to which Lonza is otherwise entitled.

10.6 Following ten (10) years after the expiration or termination of this Agreement, the Parties shall have no affirmative obligations under Clauses 10.1, 10.2 and 10.3 except with respect to trade secrets and/or know-how, for which all affirmative obligations of this Clause 10 will continue for so long as such information remains a trade secret and/or know-how under applicable law. Notwithstanding any provision to the contrary, this Clause 10.6 shall not be construed as the grant of any license or any other right to either Party to use at any time the Intellectual Property, know-how, or confidential Information of the other Party except as set forth expressly in this Agreement or in connection with the ordinary course of performance under this Agreement.

11. Audits, Inspections and Records

11.1 Once annually during the term of this Agreement, and subject to Lonza's obligations of confidentiality to Third Parties, Lonza will permit Omeros to conduct one quality assurance audit of those portions of the Facilities and Quality Systems where Services are being conducted upon reasonable advance notice and at reasonable times during regular business hours, provided, however, that Omeros may conduct additional "for cause" audits following issuance of Form FDA-483s, GMP inspection reports or similar reports delivered by Regulatory Authorities to Lonza pertaining to the Processing of Product, performance of other Services for Omeros, or the occurrence of other events which are likely to adversely affect the Processing of Product or other Services for Omeros as frequently as requested by Omeros, at reasonable times and for reasonable duration, until Lonza has corrected such deficiencies and as set out further in a separate Quality Agreement. Additionally, Lonza will permit Omeros to conduct a mock pre-approval inspection audit, not to exceed three (3) days in duration or as otherwise reasonably required, in support of Regulatory Applications or cGMP Qualified Person audit to support Qualified Person batch certification.

11.2 Each Party shall notify the other Party promptly of any inspection or inquiry by any Regulatory Authority concerning the Lonza Facilities to the extent pertaining to processing of cell banks, drug substance or drug product, any SOW or Processing of Product and as set out further in a separate Quality Agreement. Each Party shall cooperate with Regulatory Authorities in connection with any such inspection or inquiry and shall cooperate with the other Party in providing the information needed for any

response. Each Party acknowledges that it may not direct the manner in which the other Party fulfils its obligations to permit inspection by a Regulatory Authority.

11.3 Unless the Parties otherwise agree in writing, Lonza shall maintain materially complete and accurate batch, laboratory and other technical records related to Product for the minimum period required by Applicable Laws, in accordance with Lonza's standard operating procedures and as set out further in the Master Batch Record and the Quality Agreement.

11.4 Lonza and Omeros shall allocate responsibility for complying with cGMP (if applicable) between themselves as set forth in the Quality Agreement. Each Party shall provide the other with all reasonable assistance and take all actions reasonably requested by the other to enable the requesting Party to comply with any Applicable Laws relating to the performance by a Party of its obligations hereunder.

11.6 Omeros shall be solely responsible for and will obtain all permits and licenses required by any Regulatory Authority with respect to the Product and any Services under this Agreement for which Omeros is responsible, including any product licenses, applications and amendments in connection therewith. Lonza will be responsible to maintain all permits and licenses required by any Regulatory Authorities in the United States, the EU and national and local jurisdictions in which the Lonza Facility is located, with respect to the Lonza Facility generally. During the Term, Lonza will assist Omeros with all regulatory matters relating to Services under this Agreement, at Omeros' request and at Omeros' expense. Each Party intends and commits to cooperate to satisfy all Applicable Laws relating to Services under this Agreement.

12. Term and Termination

12.1 Term. This Agreement shall commence on the Effective Date and shall expire five (5) years after Launch of Product in in either US or EU territory unless terminated earlier as provided herein, or by mutual written agreement of the Parties (the "Initial Term").

12.1.1 Three (3) years prior to the end of the Initial Term, Omeros shall provide written notice to Lonza if it wishes not to extend the Agreement for a further four (4) years (an "Extension Term") and absent such notice the Agreement shall automatically extend for the further four (4) years The Initial Term and any Extension Term are together referred to herein as the "Term".

12.2 If it becomes apparent to either Lonza or Omeros at any stage in the provision of the Services that it will not be possible to obtain First Approval of the Product from the Facility and written notice of such has been provided to the other Party, following such written notice a[***] day period shall be allowed for good faith discussion and attempts to resolve such problems. If such problems are not resolved within such period, Lonza and Omeros shall each have the right to terminate the Agreement forthwith by notice in writing. In the event of such termination, Omeros shall pay to Lonza all amounts owed under Purchase Orders for Batches ordered that have been cancelled by Omeros and applicable SOWs for Services performed in accordance with the SOW and this Agreement by Lonza prior to such termination (including a pro rata proportion of the Price for any stage of the Services which is in process at the date of termination) and all expenses reasonably incurred by Lonza in giving effect to such termination, including the costs of terminating any commitments entered into and in accordance the Agreement, [***].

12.3 The obligation to make payment under Clause 12.2 shall be reduced (retrospectively, and hence Lonza shall make an appropriate refund to Omeros) to the extent that Lonza mitigates its loss in this regard (and Lonza shall use commercially reasonable efforts to mitigate its loss and shall promptly notify Omeros of any such mitigation). This provision shall not entitle Omeros to be refunded an amount greater than that paid by Omeros to Lonza pursuant to this Clause 12 and Lonza shall be entitled to deduct from the amount due to be refunded to Omeros its reasonable personnel and associated costs in attempting to mitigate its loss.

12.4 For the avoidance of doubt activities relating to cGMP fermentation shall be deemed to commence with the date of removal of the vial of cells from frozen storage for the performance of the fermentation.

12.5 The Parties may each terminate the Agreement for cause forthwith by notice in writing to the other Party upon the occurrence of any of the following events:

(a) if the other commits a material breach of the Agreement (which shall include a breach of the warranties set out in Clause 9 above) which in the case of a breach capable of remedy is not remedied within [***] days of the receipt by the other of notice identifying the breach and requiring its remedy (reasonable efforts to cure said breach shall be made within [***] days of receipt of notice); or

(b) if the other ceases for any reason to carry on business or compounds with or convenes a meeting of its creditors or has a receiver or manager appointed in respect of all or any part of its assets or is the subject of an application for an administration order or of any proposal for a voluntary arrangement or enters into liquidation (whether compulsorily or voluntarily) or undergoes any analogous act or proceedings under foreign law; or

(c) if the Product is withdrawn from US and EU markets following First Approval, any Batches ordered at the time of termination may be cancelled by Omeros and shall be subject to the termination provisions herein and any Raw Materials received or irrevocably committed shall be paid to the extent specified in the termination provisions herein.

12.6 Consequences of termination.

12.6.1 In the event of termination of this Agreement without cause by Omeros, all Services and Batches ordered pursuant to a Purchase Order shall be deemed to have been cancelled and Omeros shall pay Lonza for:

(a) all Services rendered up to the date of termination, including in respect of any Product in-process;

(b) all costs incurred through the date of termination, including Raw Materials costs and Raw Materials Fees for Raw Materials used or purchased or to which Lonza is irrevocably committed for use in connection with the Services;

(c) all unused Raw Materials and Resins shall be paid for by Omeros within [***] days of invoice and at Omeros' option will either be: (a) held by Lonza for future use for the production of Product; (b) delivered to Omeros; or (c) disposed of by Lonza.

12.6.2 *Termination by Lonza under Clause 12.5(a) or 12.5(b).* Upon termination of this Agreement by Lonza under Clause 12.5(a) or 12.5(b), subject to Lonza's obligations under Clause 12.7, Omeros shall pay to Lonza: (a) Termination Fees of any unpaid portions of [***]% of all Binding Orders in effect on the notification date of such termination for which Services have commenced and/or at least partial payment has been made by Omeros, less the amount of any such slots that Lonza is able to resell, (b) Termination Fees of [***]% of all Binding Orders placed but for which Services have not yet commenced and for which Omeros has not yet made any payment, less the amount of any such slots that Lonza is able to resell, and (c) for all Services provided but not paid as of the effective date of termination (including a pro-rata proportion of the Price for any stage of the Services which is in progress at the date of the termination).

12.6.3 *Termination by Omeros under Clause 12.5(a) or 12.5(b).* Upon termination of this Agreement by Omeros under Clause 12.5(a) or 12.5(b) all Binding Orders shall be deemed cancelled without any Termination Fees and Omeros shall have no further obligation to Lonza under this Agreement, except that Customer shall pay to Lonza: (a) for all Services not under dispute provided but not paid as of the effective date of termination (including a pro-rata proportion of the Price for any stage of the Services which is in progress at the date of the termination); and (b) the costs of any non-cancellable commitments of subcontractors and External Laboratories; and (c) all expenses reasonably incurred by Lonza in giving effect to such termination, in each case after reasonable efforts to mitigate all such expenses, including the costs of terminating any non-cancellable commitments entered into under the Agreement that cannot be cancelled despite reasonable efforts to do so or cannot be re-purposed for other customers.

12.6.4. *Termination due to Market Withdrawal*. If Omeros withdraws the Product from the U.S. and European Union markets or is directed to do so by any regulatory agency and as a result, Omeros or Lonza terminates the Agreement in accordance with Clause 12.5(c), then Omeros shall pay a termination fee in the amount of [***]% of the Batch Price for all Batches under a Binding Order. Lonza shall use commercially reasonable efforts to try and secure a replacement reservation from a new project, whilst observing its contractual commitments of other customers, and if it is able to secure such replacement reservation Omeros shall be relieved proportionally of its obligation to pay a termination fee.

12.7 Upon the termination of the Agreement for whatever reason:

(a) Lonza shall promptly return to Omeros all Omeros Information and shall dispose of or return to Omeros the Omeros Materials (and where supplied by Omeros the Cell Line) and any materials therefrom, as directed by Omeros;

(b) Omeros shall promptly return to Lonza all Lonza Know-How it has received from Lonza, except for that included as part of license provided for in Clauses 2.8(a), and 2.8 (b), as applicable, or as part of the license to the New General Application Intellectual Property provided for in Clause 8.4;

(c) Omeros shall not thereafter use or exploit the Lonza Patent Rights or the Lonza Know-How in any way whatsoever, except for that included as part of license provided for in Clauses 2.8(a), and 2.8 (b), as applicable, or as part of the license to the New General Application Intellectual Property provided for in Clause 8.4; and

(d) Lonza and Omeros shall do all such acts and things and shall sign and execute all such deeds and documents as the other may reasonably require to evidence compliance with this Clause 12.7.

12.8 Omeros will have the right upon its request, during the term of or within [***] following expiration or termination of this Agreement, to transfer the Cell Line and Process, to itself and any Third Party for the manufacture of that Product (but no other product) that:

(a) is an IP-Respecting Entity;

(b) is listed on Schedule 3 hereto, as the same may be updated from time-to-time by written agreement of the Parties; or

(c) is consented to by Lonza in writing, such consent not to be unreasonably withheld or delayed, and Lonza shall not be considered to be unreasonably withholding its consent if (inter alia) Omeros wishes to transfer the Cell Line and the Process to any legal person or entity which is not an IP-Respecting Entity;

provided always, however, to the extent such technology transfer includes Lonza's Confidential Information, Lonza's Intellectual Property and/or New General Application Intellectual Property such technology transfer shall be subject to a royalty and licensing fee for the purchase of media and feeds as provided for in Clauses 2.8(a) or 2.8(b), as applicable, and at all times shall also be subject to the outline technology transfer terms set forth in Schedule 2 hereto.

Lonza shall diligently provide reasonably necessary documents to complete such technology transfer and reasonable assistance to complete such technology transfer, provided that Omeros shall reimburse Lonza for any costs based on Lonza's standard full-time employee rate for such support which is applicable at the date of such technology transfer and the outline technology transfer terms of Schedule 2.

For purposes of clarity, the outline technology transfer terms of Schedule 2 shall not apply if Omeros transfers the Cell Line to a Third Party without any transfer of the Process.

12.9 Termination of this Agreement for whatever reason shall not affect the accrued rights of either Lonza or Omeros arising under or out of this Agreement and all provisions which are expressed to survive the Agreement shall remain in full force and effect.

13. Force Majeure

13.1 If either Party is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure it shall give written notice thereof to the other Party specifying the matters constituting Force Majeure together with such evidence as it reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue, and it shall be excused from the performance or the punctual performance of such obligations as the case may be from the date of such notice for so long as such cause of prevention or delay shall continue. The Party that may invoke this clause shall use commercially reasonable efforts to reinstate its ongoing obligations to the other Party as soon as practicable. If the cause(s) shall continue unabated for 180 days, then both Parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s) and if not resolvable either Party shall have the right to terminate this Agreement.

13.2 The expression "Force Majeure" shall be deemed to include any cause affecting the performance by a Party of the Agreement arising from or attributable to acts, events, acts of God, omissions or accidents beyond the reasonable control of the Party.

14. Governing Law, Jurisdiction and Enforceability

14.1 The construction, validity and performance of the Agreement shall be governed by the laws of the State of New York, USA, and Lonza and Omeros submit to the non-exclusive jurisdiction of the US Federal Courts located in the State of New York, USA.

14.2 No failure or delay on the part of either Lonza or Omeros to exercise or enforce any rights conferred on it by the Agreement shall be construed or operate as a waiver thereof nor shall any single or partial exercise of any right, power or privilege or further exercise thereof operate so as to bar the exercise or enforcement thereof at any time or times thereafter.

14.3 Any disputes relating to issues arising from this Agreement shall, in the absence of resolution within thirty (30) days of the dispute arising, be referred to the Chief Executive Officers of Omeros and Lonza, who shall discuss the matter and attempt to resolve it by mutual consent. If the Chief Executive Officers of Omeros and Lonza cannot resolve the dispute within thirty (30) days of the matter being referred to them, either Party may, by written notice to the other Party, invoke the mediation procedure set out in Clause 14.4 below.

14.4 If a dispute arises between the Parties that the Parties cannot resolve pursuant to Clause 14.3 above, the Parties agree to attempt in good faith to resolve such dispute by mediation administered by the CPR Institute for Dispute Resolution, 366 Madison Avenue, New York, NY 10017, in New York, New York, USA. The Parties agree that they shall share equally the cost of any mediation fees, and the cost of the mediator. Each Party must bear its own attorneys' fees and associated costs and expenses. The place of any mediation shall be New York, New York, USA. If efforts at mediation are unsuccessful within sixty (60) days of either Party referring the dispute to mediation, then either Party may require that the dispute shall be resolved by binding

arbitration in accordance with the then existing commercial arbitration rules of CPR Institute for Dispute Resolution, 366 Madison Avenue, New York, NY 10017. Arbitration shall be conducted in New York, New York, USA.

14.5 Nothing in this Clause 14 shall prevent a Party from exercising any right under this Agreement, including the right of termination under Clause 12 above.

15. Notices

15.1 Any notice or other communication to be given under this Agreement shall be delivered personally or by international express courier with delivery confirmation addressed as follows:

(a) If to Lonza to:

LONZA BIOLOGICS TUAS PTE LTD
35 Tuas South Ave 6,
SG Singapore, 637377

With a copy to:

Lonza Biologics plc
228 Bath Road
Slough
Berkshire SL1 4DX
England
For the attention of: The Head of Legal Services

(b) If to Omeros to:

Omeros Corporation
201 Elliott Avenue West
Seattle, WA 98119, USA
For the attention of: General Counsel
With a concurrent copy by e-mail (which shall not constitute notice) to generalcounsel@omeros.com,

or to such other destination as either Party hereto may hereafter notify to the other in accordance with the provisions of this Clause 15.

15.2 All such notices or other communications shall be deemed to have been served as follows:

(a) if delivered personally, at the time of such delivery;

(b) if sent by first class pre-paid post, ten (10) business days (Saturdays, Sundays and Bank or other public holidays excluded) after being placed in the post.

16. Illegality

16.1 If any provision or term of this Agreement or any part thereof shall become or be declared illegal, invalid or unenforceable for any reason whatsoever:

(a) such provision shall, so far as it is illegal, invalid or unenforceable, be given no effect by the Parties and shall be deemed not to be included in this Agreement;

(b) the other provisions of this Agreement shall be binding on the Parties as if such provision was not included therein; and

(c) the Parties agree to negotiate in good faith to amend such provision to the extent possible for incorporation herein in such reasonable manner as most closely achieves the intention of the Parties without rending such provision invalid or unenforceable.

17. Miscellaneous

17.1 Lonza shall be entitled to instruct one of more of its Affiliates to perform any of Lonza's obligations contained in this Agreement within the same Lonza Facility in which Product is Manufactured, subject to Omeros' approval, which shall not be unreasonably withheld or delayed, of the use of such Affiliate at any other Facility or transfer of any aspect of Manufacturing to any other of Lonza's or its Affiliates' Facility, with no increase in costs, but Lonza shall remain fully responsible in respect of those

obligations. Subject thereto, neither Party shall be entitled to assign, transfer, charge or in any way assign, sub-contract, transfer or delegate the benefit and/or the burden of this Agreement without the prior written consent of the other which consent shall not be unreasonably withheld or delayed, save that:

(a) Lonza shall be entitled without the prior written consent of the Omeros to assign, transfer, charge, sub-contract, deal with or in any other manner make over the benefit and/or burden of this Agreement (i) to an Affiliate or (ii) to any joint venture company of which Lonza, is the beneficial owner of at least fifty percent (50%) of the issued share capital thereof or (iii) to any company with which Lonza may merge or (iv) to any company to which Lonza may transfer its assets and undertaking; provided however in each case such assignee must be an IP Respecting Entity; and

(b) Omeros shall be entitled to assign this Agreement, including all rights and obligations arising thereunder, to any Third Party that:-

(i) is an IP-Respecting Entity and is not a Competing Contract Manufacturer,

(ii) is listed on Schedule 3 hereto, as the same may be updated from time-to-time by written agreement of the Parties,

(iii) is consented to by Lonza, such consent not to be unreasonably withheld or delayed, provided that Lonza shall not be considered to be unreasonably withholding its consent if (inter alia) Omeros wishes to assign this Agreement to any legal person or entity which is (i) a Competing Contract Manufacturer, or (ii) not an IP-Respecting Entity; or

(iv) is in connection with the sale or transfer (by whatever method) of all or substantially all of the business related to the subject matter of this agreement; provided, further, that such Affiliate or Third Party, as applicable, acknowledges and assumes in writing all of the assigning Party's obligations under the Agreement. For purposes of this Clause 17.1, the terms "assign" and "assignment" shall include, without limitation (i) the sale, exchange, transfer or issuance of fifty percent (50%) or more of the outstanding stock of such Party to an Affiliate of such Party or an unrelated entity or natural person, (ii) the sale or transfer or other disposition of all or substantially all of the assets of the Party or the line of business or Product to which this Agreement relates, and (iii) a merger, consolidation, acquisition or other form of business combination. Any purported assignment in violation of the foregoing shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the respective Parties and their successors and permitted assigns.

17.2 The obligations of the Parties under Clauses 2.8 (Omeros Cell Line and Lonza Process and Omeros Cell Line and Omeros Process), 8 (Intellectual Property), 9 (Warranties and Indemnification), 10 (Confidentiality), 12.6 (consequences of termination), 12.7 (Technology Transfer), 14 (Governing Law, Jurisdiction and Enforceability) and 17 (Miscellaneous) shall survive the termination of this Agreement for any reason.

17.3 The text of any press release or other communication to be published by or in the media concerning the subject matter of the Agreement shall require the prior written approval of Lonza and Omeros.

17.4 The Agreement embodies the entire understanding of Lonza and Omeros and there are no promises, terms, conditions or obligations, oral or written, expressed or implied, other than those contained in the Agreement. The terms of the Agreement shall supersede all previous agreements (if any) which may exist or have existed between Lonza and Omeros relating to the Services, except that with respect to the process validation Batches ordered by Omeros under the Development Agreement and the commercial Batches ordered by Omeros under the Development Agreement, all terms of this Agreement shall apply to such Batches except for the price of such Batches, which shall be as set forth in the Development Agreement rather than in this Agreement.

17.5 The Parties to this Agreement do not intend that any term hereof should be enforceable by virtue of the Contracts (Rights of Third Parties) Act 1999 by any person who is not a Party to this Agreement.

17.6 The relationship of the Parties is that of independent contractors, and neither Party will incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the Parties the relationship of joint ventures, co-partners, employer/employee or principal and agent. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or contractors or for any employee benefits of any such employee or contractor.

17.7 No variation of or addition to this Agreement or any part thereof shall be effective unless in writing and signed on behalf of both Parties. Notwithstanding the above the Parties hereby confirm that amendments to the Specification shall be effective if reduced to writing and signed by the quality and/or regulatory representative of both Parties, which quality and/or regulatory representative shall be nominated from time to time by each Party.

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[***] 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

AS WITNESS the hands of the duly authorised representatives of the Parties hereto the day and year first above written.

OMEROS CORPORATION	**LONZA BIOLOGICS TUAS PTE LTD**
Signature: /s/ Gregory A. Demopulos	Signature: /s/ [***]
Printed Name: Gregory A. Demopulos, M.D.	Printed Name: [***]
Title: Chairman & CEO	Title: General Manager, [***]

[***] 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

SCHEDULE 1

PRICING

[***]

[***] 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

SCHEDULE 2

OUTLINE TERMS FOR TECHNOLOGY TRANSFER FROM LONZA TO CUSTOMERS

[***]

[***] 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

Lonza

SCHEDULE 3

APPROVED THIRD PARTIES

[***]

[***] 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 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 quarterly report on Form 10-Q 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: November 12, 2019

/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, Michael A. Jacobsen, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: November 12, 2019

/s/ Michael A. Jacobsen
Michael A. Jacobsen
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 Quarterly Report on Form 10-Q of Omeros Corporation (the "Company") for the quarter ended September 30, 2019, 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: November 12, 2019

/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 Quarterly Report on Form 10-Q of Omeros Corporation (the "Company") for the quarter ended September 30, 2019, 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: November 12, 2019

/s/ Michael A. Jacobsen
Michael A. Jacobsen
Principal Financial and Accounting Officer
