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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 March 31, 2014

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

As of May 7, 2014, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 33,912,447.

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 and Section 21E of the Securities Exchange Act of 1934 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," "may," "plan," "potential," "predict," "project," "should," "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 ability to receive regulatory approval for our New Drug Application, or NDA, and our Marketing Authorisation Application, or MAA, for OMS302, or Omidria™, in the United States and in the European Union, or EU, respectively, in 2014;*
- *our expectation that the U.S. Food and Drug Administration will approve our NDA for Omidria in the second quarter of 2014;*
- *our anticipation that we will begin marketing Omidria, if approved, in the U.S. in the second half of 2014, and that we will initiate marketing of Omidria, assuming approval of our MAA for Omidria by the European Medicines Agency and partnering in Europe, in the EU in late 2014 or the first half of 2015;*
- *our plans for sales, marketing and distribution of Omidria in the U.S., EU and other international territories;*
- *our ability to successfully complete our Phase 2 clinical trials for OMS824 and OMS721;*
- *our expectation of timing for enrollment of patients in our Phase 2 clinical trial for OMS721;*
- *our ability to initiate post-marketing studies for Omidria and additional clinical trials for OMS103, should they be necessary;*
- *whether there may be an opportunity to have OMS103 produced and commercialized by a registered outsourcing facility;*
- *our expectations regarding the clinical, therapeutic and competitive benefits of our potential products, which we refer to herein as products;*
- *our estimate regarding how long our existing cash, cash equivalents and short-term investments will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments;*
- *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 expectation that the second half of 2014 is the earliest period in which any of our products will be commercially available or generate revenue;*
- *our anticipation that we will rely on contract manufacturers to develop and manufacture our products for commercial sale;*
- *our ability to enter into acceptable arrangements with potential corporate partners;*
- *whether pediatric studies may afford Omidria an additional six months of exclusivity;*
- *whether OMS824 has the potential to be delivered as monotherapy or as an adjunct to commercially available antipsychotics;*
- *whether GPR17 may play a role in re-myelination of neurons and whether GPR17 could be an important drug target in the treatment of demyelinating disorders;*
- *our expectations about the commercial competition that our products may face;*
- *our expected financial position, performance, growth, expenses, magnitude of net losses and availability of resources;*
- *the extent of protection that our patents provide and that our pending patent applications will provide, if patents issue from such applications, for our technologies, programs and products;*
- *our involvement in potential claims, legal proceedings and administrative actions, the expected course and costs of potential claims, legal proceedings and administrative actions, and the potential outcomes and effects of potential claims, legal proceedings and administrative actions on our business, prospects, financial condition and results of operations; and*
- *our estimates regarding our future net losses, revenues, research and development expenses and selling, general and administrative expenses.*

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part II of this Quarterly Report on Form 10-Q under

the heading "Risk Factors" and in our other filings with the Securities and Exchange Commission. Given these risks, uncertainties and other factors, actual results or developments anticipated 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. These forward-looking statements 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 law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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OMEROS CORPORATION
FORM 10-Q FOR THE QUARTER ENDED March 31, 2014

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

OMEROS CORPORATION

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	March 31, 2014 (unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 567	$ 1,384
Short-term investments	51,622	12,717
Grant and other receivables	488	379
Prepaid expenses	1,312	251
Other current assets	143	86
Total current assets	54,132	14,817
Property and equipment, net	989	939
Restricted cash	679	679
Other assets	267	100
Total assets	$ 56,067	$ 16,535
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 4,926	$ 2,329
Accrued expenses	5,306	3,944
Current portion of notes payable, net of discount	—	5,600
Total current liabilities	10,232	11,873
Notes payable, net of current portion and discount	32,212	14,898
Deferred rent	8,411	8,148
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Preferred stock, par value $0.01 per share:		
Authorized shares—20,000,000 at March 31, 2014 (unaudited) and December 31, 2013;		
Issued and outstanding shares—none	—	—
Common stock, par value $0.01 per share:		
Authorized shares—150,000,000 at March 31, 2014 (unaudited) and December 31, 2013;		
Issued and outstanding shares—33,901,591 and 30,359,508 at March 31, 2014 (unaudited) and December 31, 2013, respectively	339	304
Additional paid-in capital	275,888	235,685
Accumulated deficit	(271,015)	(254,373)
Total shareholders' equity (deficit)	5,212	(18,384)
Total liabilities and shareholders' equity	$ 56,067	$ 16,535

See notes to consolidated financial statements

OMEROS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended March 31,	
	2014	2013
Revenue	$ 100	$ 1,095
Operating expenses:		
Research and development	12,017	7,127
Selling, general and administrative	3,767	3,988
Total operating expenses	15,784	11,115
Loss from operations	(15,684)	(10,020)
Investment income	2	6
Interest expense	(672)	(587)
Other income (expense), net	(288)	112
Net loss	$ (16,642)	$ (10,489)
Comprehensive loss	$ (16,642)	$ (10,489)
Basic and diluted net loss per share	$ (0.54)	$ (0.40)
Weighted-average shares used to compute basic and diluted net loss per share	30,897,039	25,908,153

See notes to consolidated financial statements

OMEROS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2014	2013
Operating activities:		
Net loss	$ (16,642)	$ (10,489)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of assets	(9)	—
Depreciation and amortization	82	67
Stock-based compensation expense	1,788	1,093
Non-cash interest expense	136	120
Warrant modification expense	452	41
Changes in operating assets and liabilities:		
Grant and other receivables	(109)	(69)
Prepaid expenses and other current and noncurrent assets	(1,060)	(75)
Accounts payable and accrued expenses	3,960	1,227
Deferred revenue	—	(970)
Deferred Rent	263	87
Net cash used in operating activities	(11,139)	(8,968)
Investing activities:		
Purchases of property and equipment	(6)	(88)
Purchases of investments	(58,839)	(3,455)
Proceeds from the sale of investments	19,934	12,250
Net cash provided by (used in) investing activities	(38,911)	8,707
Financing activities:		
Proceeds from issuance of common stock, net of offering costs	37,749	—
Net proceeds from borrowings under notes payable	12,699	—
Payments on notes payable	(1,464)	—
Proceeds from issuance of common stock upon exercise of stock options	249	22
Net cash provided by financing activities	49,233	22
Net decrease in cash and cash equivalents	(817)	(239)
Cash and cash equivalents at beginning of period	1,384	1,520
Cash and cash equivalents at end of period	$ 567	$ 1,281
Supplemental cash flow information		
Cash paid for interest	$ 691	$ 313

See notes to consolidated financial statements

OMEROS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced potential product, OMS302 or Omidria ™ for lens replacement surgery, is derived from our proprietary PharmacoSurgery® platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures. Our PharmacoSurgery platform is based on low-dose combinations of therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. In addition to Omidria, we have six other clinical-stage development programs in our pipeline, which also includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor (GPCR) drug targets and the other used to generate antibodies. For each of our programs and potential products, which we refer to herein as products, we have retained all manufacturing, marketing and distribution rights.

Omidria is being developed for use in patients undergoing intraocular lens replacement surgery. In July 2013, we submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and in September 2013, we submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Omidria. We expect the FDA to approve our NDA for Omidria in the second quarter of 2014. Assuming approval, we expect to begin marketing Omidria in the U.S. in the second half of 2014. In the European Union (EU) and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria.

Basis of Presentation

Our consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions between and among our subsidiaries have been eliminated. The accompanying unaudited 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 March 31, 2014 and for the three months ended March 31, 2014 and 2013 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Consolidated Balance Sheet at December 31, 2013 has been derived from audited financial statements but does not include all of the information and footnotes required by GAAP.

The accompanying unaudited consolidated financial statements and notes to consolidated financial statements 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, 2013 filed with the Securities and Exchange Commission (SEC) on March 13, 2014.

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, fair market value of investments, stock-based compensation expense and accruals for clinical trials 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.

Liquidity and Capital Resources

As of March 31, 2014, we had $52.2 million in cash, cash equivalents and short-term investments due, in part, to our recent receipt of the net amounts of $37.7 million from the sale of our common stock and $12.7 million of additional debt financing. We believe that our existing cash, cash equivalents and short-term investments, together with potential sales from Omidria and capital that we may be able to raise through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales, will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months.

Inventory

Capitalization of costs as inventory will begin when the product has received regulatory approval in either the U.S. or the EU. We expense inventory costs related to products as research and development expenses prior to regulatory approval.

Segments

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

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.

The basic and diluted net loss per share amounts for the three months ended March 31, 2014 and 2013 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:

	March 31,	
	2014	2013
Outstanding options to purchase common stock	6,762,948	5,356,086
Warrants to purchase common stock	609,016	609,016
Total	7,371,964	5,965,102

Note 3—Cash, Cash Equivalents and Investments

As of March 31, 2014 and December 31, 2013, all investments are classified as short-term and available-for-sale on the accompanying Consolidated Balance Sheets. We did not own any securities with unrealized loss positions as of March 31, 2014 or December 31, 2013. Investment income consists primarily of interest income.

Note 4—Fair-Value Measurements

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 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:

	March 31, 2014			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as cash equivalents	$ —	$ —	$ —	$ —
Money-market funds classified as non-current restricted cash	679	—	—	679
Money-market funds classified as short-term investments	51,622	—	—	51,622
Total	$ 52,301	$ —	$ —	$ 52,301

	December 31, 2013			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as cash equivalents	$ 213	$ —	$ —	$ 213
Money-market funds classified as non-current restricted cash	679	—	—	679
Money-market funds classified as short-term investments	12,717	—	—	12,717
Total	$ 13,609	$ —	$ —	$ 13,609

Cash held in demand deposit accounts of $567,000 and $1.2 million is excluded from our fair-value hierarchy disclosure as of March 31, 2014 and December 31, 2013, respectively. There were no unrealized gains and losses associated with our short-term investments as of March 31, 2014 or December 31, 2013. The carrying amounts reported in the accompanying Consolidated Balance Sheets for grant and other receivables, accounts payable and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

Note 5—Accrued Liabilities

Accrued liabilities consisted of the following:

	March 31, 2014	December 31, 2013
	(In thousands)	
Contract research	$ 1,727	$ 858
Employee compensation	1,476	1,346
Clinical trials	768	596
Consulting & professional fees	971	649
Other accruals	364	495
Total accrued liabilities	$ 5,306	$ 3,944

Note 6—Notes Payable

In March 2014, we entered into a new Loan and Security Agreement (the Oxford/MidCap Loan Agreement) with Oxford Finance LLC (Oxford) and MidCap Financial SBIC, LP (MidCap) pursuant to which we borrowed $32.0 million. We used approximately $19.1 million of the loan proceeds to repay all of the amounts owed by us under our then outstanding loan from Oxford and, after deducting all loan initiation costs including a $160,000 upfront loan initiation fee and lenders' legal costs, we received $12.7 million in net proceeds. The Oxford/MidCap Loan Agreement provides for monthly interest-only payments at an annual rate of 9.25% through March 1, 2015. Beginning April 1, 2015, monthly principal and interest payments of $1.0 million are due through the maturity date of March 1, 2018. In addition, the Oxford/MidCap Loan Agreement requires a $2.2 million loan maturity fee upon full repayment of the loan. We may prepay the outstanding principal balance in its entirety at any time if we pay an additional fee equal to 1.0% of the then-outstanding principal balance, which prepayment fee would be waived if we refinance the indebtedness with Oxford and MidCap and pay the loan maturity fee. As security under the Oxford/MidCap Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property.

The Oxford/MidCap Loan Agreement contains covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, pledge our intellectual property or repurchase stock. Additionally, the Oxford/MidCap Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breach, occurrence of a material adverse effect (MAE, as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgment defaults and a change of control. The occurrence of an event of default could result in the acceleration of the Oxford/MidCap Loan Agreement and, under certain circumstances, could increase our interest rate 5.0% per annum during the period of default.

MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our

inability to repay any portion of the loans in accordance with the terms of the Oxford/MidCap Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the enforceability of any material provision of the Oxford/MidCap Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce its rights and remedies under the Oxford/MidCap Loan Agreement or related agreements.

We accounted for the Oxford/MidCap Loan Agreement as a debt modification and, accordingly, the remaining unamortized debt issuance costs of $103,000 associated with the then outstanding loan with Oxford and the debt issuance costs of $244,000 associated with the Oxford/MidCap Loan Agreement are being amortized to interest expense using the effective interest method through the March 1, 2018 Oxford/MidCap Loan Agreement maturity date. Additionally, the $2.2 million maturity fee, which is treated as a debt discount, is being amortized to interest expense using the effective-interest method through March 1, 2018.

As of March 31, 2014, the remaining unamortized discount and debt issuance costs associated with the debt were $2.2 million and $339,000, respectively.

Note 7—Revenue

Revenue recognized from grants and other sources is as follows:

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Small Business Innovative Research Grants	$ 100	$ 125
Vulcan Inc.	$ —	$ 970
Total revenue	$ 100	$ 1,095

We have periodically received Small Business Innovative Research (SBIR) grants from the National Institutes of Health (NIH), which are used to support the research and development of our products. We recorded revenue related to these grants of $100,000 and $125,000 for the three months ended March 31, 2014 and 2013, respectively. As of March 31, 2014, $1.1 million of potential revenue remained available under these grants, if qualifying research is performed.

In October 2010, we entered into a platform development funding agreement with Vulcan Inc. and its affiliate (collectively, Vulcan) pursuant to which we received $20.0 million for our G protein-coupled receptor (GPCR) program. Of the funds received, $8.2 million was recorded as deferred revenue. The remaining deferred revenue of $970,000 was recognized as revenue during the first quarter of 2013.

Note 8—Commitments and Contingencies

Real Estate Obligations

We currently lease our office and laboratory space in The Omeros Building under a lease agreement with BMR-201 Elliott Avenue LLC (BMR). The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of March 31, 2014, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately $61.0 million. The remaining deferred rent balance relates to rent deferrals since the inception of our lease. Deferred rent is being amortized to research and development and selling, general and administrative expense on a straight-line basis through the term of the lease.

Development Milestones and Product Royalties

We have retained the worldwide commercial rights to all of the products in our clinical and preclinical programs. We potentially owe certain development milestones and sales based royalties on commercial sales of certain products within our pipeline. These are low-single-digit royalties based on net sales or net income as more fully described in our 2013 Annual Report on Form 10-K filed with the SEC on March 13, 2014.

In April 2010, we entered into an exclusive license agreement with Helion Biotech ApS (Helion), pursuant to which we received a royalty-bearing, worldwide exclusive license to all of Helion's intellectual property rights related to mannan-binding lectin-associated serine protease-2 (MASP-2) antibodies, polypeptides and methods in the field of inhibition of mannan-binding lectin-mediated activation of the complement system for the prevention, treatment or diagnosis of any disease or condition. We

incurred a milestone payment of $200,000 to Helion during the first quarter of 2014 related to the filing of an Investigational New Drug Application (IND) with the FDA.

Other

In the first quarter of 2013, we recorded a $900,000 expense as selling, general and administrative expense in connection with previously awarded NIH grants.

Note 9—Shareholders' Equity

Common Stock

Public Offering - In March 2014, we sold 3.5 million shares of our common stock at a public offering price of $11.50 per share in a public offering. After deducting offering expenses and underwriter discounts of $2.5 million, we received net proceeds from the transaction of $37.7 million.

MLV At-the-Market Sales Agreement - In December 2012, we entered into an at-the-market issuance sales agreement (the Sales Agreement) with MLV & Co. LLC (MLV). The Sales Agreement terminated April 16, 2014.

Warrants

The following table summarizes our total outstanding warrants as of March 31, 2014, which have a weighted average exercise price of $23.85:

Outstanding At March 31, 2014	Expiration Date	Exercise Price
197,478	September 29, 2014	$12.25
133,333	October 21, 2015	20.00
133,333	October 21, 2015	30.00
133,333	October 21, 2015	40.00
11,539	April 26, 2015	9.13
609,016		$23.85

On March 28, 2014, we extended the expiration dates of warrants to purchase 197,478 shares of our common stock at an exercise price of $12.25 per share to September 29, 2014. In March 2013, we extended the expiration dates of the same warrants by one year. We evaluated the fair value of the warrants before and after the modifications and recorded the $452,000 and $41,000 change in fair value as other expense in the accompanying Consolidated Statement of Operations and Comprehensive Loss for the three months ended March 31, 2014 and 2013, respectively.

In October 2010, in connection with the Vulcan agreement, we issued to Vulcan three warrants to purchase our common stock, each with a five-year term and exercisable for 133,333 shares, with exercise prices of $20, $30 and $40 per share, respectively.

Note 10—Stock-Based Compensation

Our 2008 Equity Incentive Plan (the 2008 Plan) provides for the grant of incentive and nonstatutory stock options, restricted stock, stock appreciation rights, performance units and performance shares to employees, directors and consultants and subsidiary corporations' employees and consultants. Options are granted with exercise prices equal to the closing fair market value of our common stock on the date of the grant. The terms of options may not exceed 10 years and options generally vest over a four-year period.

On January 1, 2014, in accordance with provisions of the 2008 Plan, the authorized shares available for grant under the 2008 Plan were increased by 1,517,975 shares. As of March 31, 2014, a total of 8,858,525 shares were reserved for issuance under our stock plans, of which 2,095,577 were available for future grants under the 2008 Plan.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. There were no stock option grants during the first quarter of 2014 or 2013.

Stock-based compensation expense has been reported in our Consolidated Statements of Operations and Comprehensive Loss as follows:

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Research and development	$ 1,011	$ 581
Selling, general and administrative	777	512
Total	$ 1,788	$ 1,093

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, 2013	6,969,303	$ 6.38		
Granted	—	—		
Exercised	(42,083)	5.93		
Forfeited	(164,272)	9.80		
Balance at March 31, 2014	6,762,948	$ 6.30	6.83	$ 39,056
Vested and expected to vest at March 31, 2014	6,526,397	$ 6.20	6.75	$ 38,315
Exercisable at March 31, 2014	4,322,288	$ 4.78	5.63	$ 31,509

At March 31, 2014, there were 2,440,660 unvested options outstanding that will vest over a weighted-average period of 2.3 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these options is $12.9 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 consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a clinical-stage biopharmaceutical company committed to discovering, developing and commercializing products targeting inflammation, coagulopathies and disorders of the central nervous system. Our most clinically advanced potential product, OMS302 or Omidria ™ for intraocular lens replacement, or ILR, is derived from our proprietary PharmacoSurgery ® platform designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures. Our PharmacoSurgery platform is based on low-dose combinations of therapeutic agents delivered directly to the surgical site throughout the duration of the procedure to inhibit preemptively inflammation and other problems caused by surgical trauma and to provide clinical benefits both during and after surgery. In addition to Omidria, we have six other clinical-stage development programs in our pipeline, which also includes a diverse group of preclinical programs as well as two additional platforms: one capable of unlocking new G protein-coupled receptor, or GPCR, drug targets and the other used to generate antibodies. For each of our programs and potential products, which we refer to herein as products, we have retained all manufacturing, marketing and distribution rights.

Products and Development Programs

We submitted for Omidria a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, in July 2013 and a Marketing Authorisation Application, or MAA, to the European Medicines Agency, or EMA, in September 2013 to allow us to market and sell Omidria in the U.S. and the European Union, or EU, respectively, for use in patients undergoing ILR. In October 2013, we announced that the FDA accepted the NDA for Omidria for filing and that the MAA for Omidria was validated by the EMA. We expect the FDA to approve our NDA for Omidria in the second quarter of 2014. Assuming approval, we expect to begin marketing Omidria in the U.S. in the second half of 2014. In November 2013, the FDA conditionally accepted Omidria as the proposed brand name for OMS302 in the U.S. and in December 2013, the EMA accepted Omidria as the proposed brand name for OMS302 in the EU. These acceptances are subject to final determination prior to approval of the respective marketing applications. For the potential commercial launch of Omidria in the U.S., if approved, we intend to develop our own internal sales and marketing management team and to utilize marketing consultants and a contract sales organization to call on surgeons, hospitals and ambulatory surgery centers in the U.S. In the EU and other international territories, we plan to enter into one or more partnerships for the marketing and distribution of Omidria. Assuming approval of our MAA for Omidria by the EMA and partnering in Europe, we anticipate the initiation of EU marketing and sales of Omidria in late 2014 or in the first half of 2015. We have discussed with the FDA and EMA the design for pediatric studies for Omidria, which may afford Omidria an additional six months of exclusivity in each of these territories if completed successfully. In addition, we are exploring the potential role of Omidria in the management of intraoperative floppy iris syndrome, or IFIS.

Behind Omidria in our pipeline, we have a series of other development programs targeting pain, inflammation, coagulopathies and disorders of the central nervous system. We have the following six additional clinical-stage programs in our pipeline: (1) OMS103 for reducing inflammatory pain following arthroscopic partial meniscectomy, which has completed one Phase 3 trial in patients undergoing this procedure, (2) our lead phosphodiesterase 10, or PDE10, inhibitor OMS824 for the treatment of schizophrenia, which is in a Phase 2 clinical program, (3) our lead PDE10 inhibitor OMS824 for the treatment of Huntington's disease, which is in a Phase 2 clinical program, (4) our lead MASP-2 antibody OMS721, which is in a Phase 2 clinical program in patients with thrombotic microangiopathies, or TMAs, (5) our PPARγ program, in which three Phase 2 clinical trials are being conducted by our collaborators to evaluate a PPARγ agonist, alone or in combination with other agents, for their effects on smoking, as well as in the abuse liability of oxycodone or heroin and (6) our PharmacoSurgery product OMS201 for use during urological procedures, including uroendoscopic procedures, which has completed a Phase 1/Phase 2 clinical trial in 2010 and is not currently in active clinical trials. Of these six additional clinical programs, we currently are focused on OMS103, OMS824 and OMS721.

OMS103, our second PharmacoSurgery product, is being developed for use during arthroscopic procedures, including partial meniscectomy surgery. We are redesigning our Phase 3 clinical program in arthroscopic partial meniscectomy surgery to include reduction of early postoperative pain as the primary endpoint. In addition, we are evaluating alternative approaches for making OMS103 commercially available, such as through a registered outsourcing facility without the need to conduct any additional clinical trials.

OMS824 is in two Phase 2 clinical programs, one for schizophrenia and one for Huntington's disease. We are conducting an ongoing Phase 1 clinical program evaluating the safety, tolerability and pharmacokinetics of OMS824 in healthy subjects as

well as a clinical trial to evaluate target occupancy of OMS824 using PET scans in healthy subjects by measuring the extent to which OMS824 binds to PDE10 in the brain. In January 2014, we announced positive results from our OMS824 Phase 2a clinical trial in which OMS824 was well tolerated and demonstrated comparable tolerability and systemic pharmacokinetics when administered alone and concomitantly with approved antipsychotic agents in patients with stable schizophrenia, opening the potential for OMS824 to be delivered as monotherapy or as an adjunct to commercially available antipsychotics. OMS824 has received Orphan Drug designation for the treatment of Huntington's disease and Fast Track designation for the treatment of cognitive impairment in patients with Huntington's disease. We also are seeking Fast Track designation for OMS824 for schizophrenia.

For OMS721, in February 2014 we reported positive data from our Phase 1 clinical trial. In March 2014, we submitted to the FDA an IND application to evaluate OMS721 in patients with complement-mediated TMAs. That same month, we announced positive data using OMS721 in *ex vivo* studies of endothelial activation relevant to the pathophysiology of human atypical hemolytic uremic syndrome, or aHUS, a form of TMA. These studies showed that OMS721 significantly inhibited complement deposition in the system using serum samples from aHUS patients obtained during the acute phase of disease ($p<0.01$) and during remission ($p<0.001$) compared to untreated controls. In April 2014, the IND was cleared by the FDA, and a Phase 2 clinical program is currently underway with enrollment of TMA patients expected to begin later this quarter. OMS721 has received Orphan Drug designation for inhibition of complement-mediated TMAs.

Our preclinical programs include: (1) our PDE7 program in which we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders, (2) our Plasmin program in which we are advancing novel antifibrinolytic agents for the control of blood loss during surgery or resulting from trauma as well as for other hyperfibrinolytic states (e.g., liver disease), (3) our proprietary *ex vivo* antibody platform and (4) our orphan GPCR platform in which we are working to complete high-throughput surrogate de-orphanization of orphan GPCRs, identifying small-molecule compounds that bind and functionally interact with the receptors and to develop products that act at these new potential drug targets. To date, we have identified and confirmed sets of small-molecule compounds that interact selectively with, and modulate signaling of, 54 Class A orphan GPCRs, as well as two Class B GPCRs (glucagon-like peptide-1 receptor, or GLP-1R, and parathyroid hormone 1 receptor, or PTH-1R). We have initiated medicinal chemistry efforts to optimize compounds against several orphan GPCRs including GPR17, which appears to play a critical role in re-myelination of neurons and could be an important drug target in the treatment of demyelinating disorders such as multiple sclerosis as well as traumatic brain and spinal cord injuries.

Financial Summary

The majority of our operating expenses to date have been for research and development activities. Research and development expenses consist of costs associated with research activities as well as costs associated with our product development efforts, which include clinical trial and third-party manufacturing services. Internal research and development costs are recognized as incurred. Third-party research and development costs are expensed at the earlier of when the contracted work has been performed or when upfront and milestone payments are made. Research and development expenses include:

- employee and consultant-related expenses, which include salaries and benefits, and non-cash stock-compensation;
- external research and development expenses incurred pursuant to agreements with third-party manufacturing organizations, clinical research organizations, or CROs, clinical trial sites, and collaborators or licensors;
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and depreciation of leasehold improvements and equipment; and
- third-party supplier expenses including laboratory and other supplies.

We recognized net losses of $16.6 million and $10.5 million for the three months ended March 31, 2014 and 2013, respectively. These losses have resulted principally from expenses incurred in connection with research and development activities, consisting primarily of clinical trials, manufacturing services and preclinical studies associated with our current products. Compared to 2013, we expect our net losses to increase as we continue to add personnel for our anticipated growth and to prepare for the commercial launch of Omidria in the U.S., if it is approved, to advance our clinical trials, and expand our research and development efforts. As of March 31, 2014, our accumulated deficit was $271.0 million, total shareholders' equity was $5.2 million and we had $52.2 million in cash, cash equivalents and short-term investments.

Results of Operations

Revenue

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Small Business Innovative Research Grant	$ 100	$ 125
Vulcan Inc.	—	970
Total Revenue	$ 100	$ 1,095

Historically, our revenue has consisted of grant funding and revenue recognized in connection with funding received from third parties. Other than grant funding, we do not expect to receive any revenue from our products unless we receive regulatory approval and commercialize our products or enter into collaborative agreements for the development and commercialization of our products. Omidria, our most advanced product, is currently under review for marketing authorization by both the FDA and the EMA. We expect the FDA to approve our NDA for Omidria in the second quarter of 2014. We do not expect Omidria to be commercially available, if at all, before the second half of 2014 in the U.S. and late in 2014 or in the first half of 2015 in Europe. With respect to the EU, we do not expect to begin marketing Omidria until we have secured a partner with European commercial operations. We continue to pursue government and private grant funding as well as collaboration funding for our products and research programs.

The decrease in revenue during the three months ended March 31, 2014 was due to lower revenue recognized from our GPCR program funding agreement with Vulcan Inc. and its affiliate, which we collectively refer to as Vulcan. We recognized the remaining deferred revenue in connection with the Vulcan agreement as revenue in the first quarter of 2013. No further revenue remains to be recognized under the agreement as of March 31, 2014.

Research and Development Expenses

Our research and development expenses can be divided into direct external expenses, which include clinical research and development and preclinical research and development activities; internal, overhead and other expenses; and stock-based compensation expense. The following table illustrates our expenses associated with these activities:

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Direct external expenses:		
Clinical research and development:		
OMS824	$ 3,620	$ 374
OMS721	2,033	—
Omidria	1,139	887
OMS103	16	266
Other clinical programs	8	11
Total clinical research and development	6,816	1,538
Preclinical research and development	312	1,600
Total direct external expenses	7,128	3,138
Internal, overhead and other expenses	3,878	3,408
Stock-based compensation expense	1,011	581
Total research and development expenses	$ 12,017	$ 7,127

The increase in total research and development expenses during the three months ended March 31, 2014 compared to the same quarter in the prior year was due primarily to higher clinical material manufacturing and clinical expenses related to our Phase 1 and Phase 2 clinical trials evaluating OMS824 for the treatment of schizophrenia and Huntington's disease, higher clinical material manufacturing and clinical expenses related to our Phase 2 clinical trial evaluating OMS721 in patients with TMAs, higher expense related to non-cash stock compensation, and higher employee costs. Non-cash stock compensation

expense increased for the three months ended March 31, 2014 compared to the same period in 2013 due to the grant of stock options during the third quarter of 2013 related to annual performance reviews. These increased expenses for the three months ended March 31, 2014 compared to the same period in 2013 were partially offset by lower clinical research and development expenses related to reduced preclinical activity on our PDE7 program and the completion of our OMS103 Phase 3 clinical trial in December 2012, for which there were costs related to close out during the first quarter of 2013. We expect our research and development expenses to remain constant or increase slightly in the near term as we continue to advance OMS824, OMS721, OMS302 and OMS103 through further clinical development and initiate clinical trials for our Plasmin and PDE7 programs.

Direct external clinical research and development expenses consist primarily of expenses incurred pursuant to agreements with third-party manufacturing organizations, CROs, clinical trial sites, collaborators, licensors and consultants. Direct external preclinical research and development expenses consist primarily of third-party manufacturing organizations and CROs, laboratory supplies and consulting. 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. Our internal resources, employees and infrastructure are not directly tied to any individual research project and are deployed across multiple clinical and preclinical projects we are advancing in parallel.

At this time, due to the inherently unpredictable nature of our preclinical and clinical development activities and given the early stage of many of our preclinical development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our products. Clinical development timelines, the probability of success and development costs can differ materially as expectations change. While we currently are focused on advancing our product development programs, our future research and development expenses will depend on the preclinical or clinical success of each product as well as ongoing assessments of each product's commercial potential. In addition, we cannot forecast with any degree of certainty which products 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.

The lengthy process of completing clinical trials and seeking regulatory approval for our products requires the expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations, financial condition and liquidity. We do not expect any of our current products to be commercially available before the second half of 2014, if at all. Because of the factors above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our research and development projects.

Selling, General and Administrative Expenses

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Selling, general and administrative, excluding stock-based compensation expense	$ 2,990	$ 3,476
Stock-based compensation expense	777	512
Total selling, general and administrative expenses	$ 3,767	$ 3,988

The decrease in selling, general and administrative expenses during the three months ended March 31, 2014 was primarily due to a $900,000 expense recorded in the first quarter of 2013 in connection with previously awarded grants from the National Institutes of Health, or NIH. Exclusive of the NIH expense, selling, general and administrative expenses increased from the first quarter of 2013 compared to the same quarter in 2014. This increase was primarily due to non-cash stock compensation costs and expenses related to the preparation for our planned commercial launch of Omidria in the U.S. We expect our selling, general and administrative expenses to increase in the near term as we prepare for the potential commercial launch of Omidria in the second half of 2014.

Interest Expense

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Interest expense	$ 672	$ 587

The increase in interest expense during the three months ended March 31, 2014 was due primarily to a higher average balance on our note payable during the 2014 period due to entering into a new loan agreement, or the Oxford/MidCap Loan Agreement, with Oxford and MidCap Financial SBIC, LP, or MidCap, in March 2014, pursuant to which we increased the aggregate amount of our outstanding indebtedness.

Other Income (Expense), Net

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Other income (expense), net	$ (288)	$ 112

Other income (expense) principally includes rental income and costs associated with warrant modifications. The decrease in other income (expense) during the three months ended March 31, 2014 is due to an increase in warrant modification expenses from $41,000 in the first quarter of 2013 to $452,000 in the same quarter in 2014 when we extended the exercise period of these warrants by one year and six months, respectively. The warrant modification expenses in each period relate to extensions of the expiration dates of these warrants to purchase up to 197,478 shares of common stock in aggregate.

Financial Condition - Liquidity and Capital Resources

As of March 31, 2014, we had $52.2 million in cash, cash equivalents and short-term investments that are held principally in interest-bearing instruments, including money-market accounts. Cash in excess of our immediate requirements is invested in accordance with established guidelines to preserve principal and maintain liquidity.

In March 2014, we sold 3.5 million shares of our common stock in a public offering at a public offering price of $11.50 per share. After deducting offering expenses and underwriter discounts, we received net proceeds from the transaction of $37.7 million. Also in March 2014, we terminated our existing loan agreement with Oxford and entered into the Oxford/MidCap Loan Agreement, whereby we received $12.7 million in additional funds and deferred the repayment of any principal under the new loan agreement until April 1, 2015.

The audit report covering our 2013 consolidated financial statements contained a “going concern” explanatory paragraph based on our losses and financial condition as of December 31, 2013. Subsequent to the March 13, 2014 issuance of the audit report, we received $37.7 million from the sale of our common stock in the public offering described above. Also as stated above, we received $12.7 million in incremental borrowings under the Oxford/MidCap Loan Agreement in March 2014. We believe that our existing cash, cash equivalents and short-term investments, together with potential sales of Omidria, and funds that we may be able to raise through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales, will be sufficient to fund our anticipated operating expenses, capital expenditures and note payments for at least the next 12 months. If we are unable to raise capital as and when needed, such failure could have a negative impact on our financial condition.

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Selected cash flow data		
Cash provided by (used in):		
Operating activities	$ (11,139)	$ (8,968)
Investing activities	(38,911)	8,707
Financing activities	49,233	22

Operating Activities. Expenditures related to operating activities were primarily for research and development and selling, general and administrative expenses in support of our operations. Net cash used in operating activities increased for the three months ended March 31, 2014, as compared to the same period in 2013 by $2.2 million, primarily due to higher operating expenses leading to an increase in our net loss. Other activities impacting the overall increase in net cash used in operating activities between the comparative periods was a $2.7 million increase in accounts payable and accrued expenses, a $985,000 increase in prepaid expenses and other current and noncurrent assets and a $970,000 decrease in deferred revenue.

Investing Activities. Investing activities, other than the purchases of property and equipment, consist primarily of purchases and sales of short-term investments. Cash flows from investing activities primarily reflect cash used to purchase short-term investments and receipts 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 these cash flows to be important to the understanding of our liquidity and capital resources.

Net cash used in investing activities in the three months ended March 31, 2014 was primarily due to the purchase of short-term investments with the proceeds we received from the sale of common stock in our public offering and borrowings under the Oxford/MidCap Loan Agreement, both of which occurred in March 2014, and is partially offset by the sale of short-term investments.

Financing Activities. Net cash provided from financing activities in the three months ended March 31, 2014 was due primarily to the $37.7 million of net proceeds that we received from the sale of 3.5 million shares of common stock in our public offering and the net additional borrowings of $12.7 million under the Oxford/MidCap Loan Agreement. During the 2013 period, cash provided by financing activities was due to the $22,000 in net proceeds we received from issuance of common stock upon exercise of stock options. In December 2012, we amended the Oxford notes to provide for interest-only payments through December 31, 2013 and, as a result, for the three months ended March 31, 2013, no cash was used for principal payments on the notes.

Funding Requirements

Because of the numerous risks and uncertainties associated with the development and commercialization of our products, and to the extent that we may or may not enter into collaborations with third parties to participate in the development and commercialization of one or more of those products, we are unable to estimate the amounts of increased capital requirements and operating expenditures required in the future. Our future operating and capital requirements will depend on many factors, including:

- the progress and results of our preclinical and clinical programs;
- the costs of commercialization activities, including product manufacturing, marketing, sales and distribution and related support activities;
- the commercial success of Omidria, if and when Omidria is approved for sale in the U.S. and/or the EU;
- the cost, timing and outcomes of the regulatory processes for our products;
- the extent to which we raise capital by selling our stock or entering into other forms of financing including debt agreements;
- the terms and timing of receipts or payments related to collaborative or licensing agreements we have or may establish;
- the hiring of new employees to support our continued growth;
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to these types of transactions; and
- the cost of preparing, filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

We expect our continued operating losses to result in an increase in the total amount of cash used in operations until at least the time that Omidria, if approved, becomes cash flow positive, which may be in several years if at all. To meet our future capital requirements, we will need to fund our future cash needs through public or private equity sales, debt financings or corporate collaboration and licensing arrangements. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we do not raise additional capital through equity or debt financings or collaborations and licensing arrangements, we may be required to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts. We currently do not have any commitments for future external equity or debt funding.

MLV At-the-Market Agreement

In December 2012, we entered into an at-the-market issuance sales agreement with MLV & Co. LLC, or MLV. This sales agreement expired on April 16, 2014.

Loan and Security Agreement

In March 2014, we entered into the Oxford/MidCap Loan Agreement with Oxford and MidCap, pursuant to which we borrowed $32.0 million. We used approximately $19.1 million of the loan proceeds to satisfy all of the amounts owed by us under our then-outstanding loan from Oxford and, after deducting all loan initiation costs including a $160,000 upfront loan initiation fee and lenders' legal costs, we received $12.7 million in net proceeds. Part of the costs paid included $520,000 for the prorated portion of the $1.4 million loan maturity fee payable under our then-outstanding loan agreement with Oxford, with no further obligation for the remaining $880,000. We intend to use the loan proceeds for general corporate purposes and working capital.

Interest on the amounts borrowed under the Oxford/MidCap Loan Agreement accrues at an annual fixed rate of 9.25%. Payments due under the Oxford/MidCap Loan Agreement are interest-only, payable monthly, in arrears, through March 1, 2015. Beginning April 1, 2015, 36 payments of principal and interest are payable monthly, in arrears. All unpaid principal and accrued and unpaid interest are due and payable on March 1, 2018.

In consideration for the lenders agreeing to provide us with a one-year period of interest-only payments, we will be required to pay the lenders a final payment fee equal to 7.00% of the original principal amount borrowed under the Oxford/MidCap Loan Agreement (i.e., $2.2 million), less any portion of the fee previously paid in connection with a prepayment. We may prepay all or a portion of the outstanding principal and accrued and unpaid interest at any time upon prior notice to the lenders and the payment of a fee equal to 1.00% of the prepaid principal amount in addition to the pro rata portion of the final payment fee attributable to the prepaid principal amount. As security for our obligations under the Oxford/MidCap Loan Agreement, we granted Oxford, as collateral agent for the lenders, a security interest in substantially all of our assets, excluding intellectual property.

The Oxford/MidCap Loan Agreement contains covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, pledge our intellectual property or repurchase stock. Additionally, the Oxford/MidCap Loan Agreement includes events of default regarding non-payment, inaccuracy of representations and warranties, covenant breach, occurrence of a material adverse effect, or MAE (as defined below), cross default to material indebtedness, bankruptcy or insolvency, material judgment defaults and a change of control. The occurrence of an event of default could result in the acceleration of the Oxford/MidCap Loan Agreement and, under certain circumstances, could increase our interest rate 5.0% per annum during the period of default.

MAE is defined as a material adverse effect upon (i) our business operations, properties, assets, results of operations or financial condition of Omeros, taken as a whole with respect to our viability, that reasonably would be expected to result in our inability to repay any portion of the loans in accordance with the terms of the Oxford/MidCap Loan Agreement, (ii) the validity, perfection, value or priority of the lenders' security interest in the collateral, (iii) the enforceability of any material provision of the Oxford/MidCap Loan Agreement or related agreements, or (iv) the ability of the lenders to enforce their rights and remedies under the Oxford/MidCap Loan Agreement or related agreements. We considered the MAE definition and believe that the MAE clause has not been triggered as of March 31, 2014.

Contractual Obligations and Commitments

We currently lease our office and laboratory space in The Omeros Building under a lease agreement with BMR-201 Elliott Avenue LLC. The initial term of the lease ends in November 2027 and we have two options to extend the lease term, each by five years. As of March 31, 2014, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately $61.0 million and we have received net lease incentives of $4.6 million, which were recorded as deferred rent on our accompanying consolidated balance sheet.

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 the events triggering the commencement of payment obligations will occur. See Note 8 to our consolidated financial statements in our 2013 Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC on March 13, 2014 for a description of the agreements that include these royalty and milestone payment obligations.

Critical Accounting Policies and Significant Judgments and Estimates

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the U.S. The preparation of our financial statements requires management to make estimates and assumptions that affect the amounts reported in the

financial statements and accompanying notes. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from those estimates. An accounting policy is considered critical if it is important to a company's financial condition and results of operations and if it requires the exercise of significant judgment and the use of estimates on the part of management in its application. Although we believe that our judgments and estimates are appropriate, actual results may differ materially from our estimates.

In relation to our planned commercial launch of Omidria, capitalization of costs as inventory will begin when Omidria has received regulatory approval in either the U.S. or Europe. We expense inventory costs related to products as research and development expenses prior to regulatory approval.

For a more detailed listing of our other critical accounting estimates, refer to our 2013 Annual Report on Form 10-K filed with the SEC on March 13, 2014.

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 and notes payable. 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 March 31, 2014, we had cash, cash equivalents and short-term investments of $52.2 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 materially 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 do not believe that we are 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 and financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, as of March 31, 2014. 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 March 31, 2014, 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 1A. RISK FACTORS

Our business, prospects, financial condition or operating results could be materially adversely affected by any of the risks and uncertainties described below, as well as other risks not currently known to us or that we currently deem immaterial. You should carefully consider these risks before making an investment decision. The trading price of our common stock could decline due to any of these risks and you may lose all or part of your investment. In assessing the risks described below, you should also refer to the other information contained in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2013.

Risks Related to Our Products, Programs and Operations

We are focusing a significant portion of our activities and resources on Omidria and our success may largely depend on our ability to obtain regulatory approval.

We are a biopharmaceutical company with no products approved for commercial sale and we have not generated any revenue from product sales. We have incurred, and expect to continue to incur, significant costs relating to the development of our lead PharmacoSurgery product, Omidria, for use during ILR procedures. We intend to focus a significant portion of our activities and resources on gaining regulatory approval and, if approved, commercializing Omidria, and we believe that a substantial portion of the value of our company relates to our ability to obtain marketing approval for and commercialize this product.

We have submitted an NDA with the FDA and an MAA with the EMA for Omidria, and both are currently under review. The regulatory process is subject to substantial agency discretion and risks, including those described later in these risk factors. Either agency may decide not to approve our application, or to require us to obtain additional data regarding Omidria and to resubmit our marketing application(s), further delaying our ability to market and generate revenue from the sale of Omidria.

If there are any negative decisions or delays in the regulatory process, the market price of our common stock could decline significantly.

Even if we receive regulatory approval for Omidria or our other products, we cannot be certain that we will successfully commercialize these products.

We have invested a significant portion of time and financial resources in the development of Omidria and our other products. We anticipate that our ability to generate revenues will depend on the commercial success of our products, including Omidria, if approved, which in turn will depend on several factors, including our ability to:

- generate commercial sales of our products, if approved, through our own sales force or contract sales organizations, or collaborations with pharmaceutical companies, that we may establish;
- establish effective marketing programs and build brand identity;
- obtain acceptance of our products by physicians, patients and third-party payors and obtain and maintain distribution of our products;
- establish and maintain agreements with distributors on commercially reasonable terms; and
- demonstrate commercial manufacturing capabilities necessary to meet the commercial demand for a product and maintain commercial manufacturing arrangements with third-party manufacturers.

We will continue to incur significant and increasing costs as we continue to support the potential commercial launch of Omidria, if approved. If we fail to commercialize successfully this product or the other products in our pipeline, if approved, or if we are significantly delayed in doing so, we may be unable to generate sufficient revenues to grow our business and our business, financial condition and results of operations will be materially and adversely affected.

Our existing and future products, including Omidria, may never achieve market acceptance.

Even if we receive regulatory approvals for the commercial sale of one or more of our existing or future products, including Omidria, the commercial success of these products will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community. If our products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including:

- our ability to provide acceptable evidence of safety, efficacy and product quality;

- the availability and relative cost and efficacy of alternative and competing treatments;
- the effectiveness of our marketing and distribution strategy to, among others, hospitals, surgery centers, physicians and/or pharmacists;
- the prevalence of the condition for which the product is approved or frequency of the related surgical procedure;
- the acceptance by physicians of each product as a safe and effective treatment;
- the perceived advantages over alternative treatments;
- the relative convenience and ease of administration;
- the availability of adequate reimbursement by Medicare and other third parties;
- the frequency and severity of adverse side effects; and
- publicity concerning our products or competing products and treatments.

Further, the number of procedures in which any of our PharmacoSurgery products, if approved, would be used may be significantly less than the total number of such procedures performed. If our products do not receive sufficient levels of acceptance from physicians, patients, third-party payors and other members of the medical community, it is unlikely that we will ever become profitable. If we are unable to increase market penetration of our products, our growth prospects would be significantly harmed.

We are subject to extensive government regulation, including the regulations associated with approval for marketing of our products.

Both before and after approval of our products, we, our products, and our suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the U.S. and other countries, covering, among other things, testing, manufacturing, quality control, clinical trials, labeling, advertising, promotion, distribution, and import and export. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: warning letters; unanticipated expenditures; delays in approval or refusal to approve a product; product recall or seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties. We, the FDA or an independent Institutional Review Board or Ethics Committee may suspend or terminate human clinical trials at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk or because of the way in which the investigators on which we rely carry out the trials.

The FDA has not approved any of our products for sale in the U.S. Obtaining FDA approval requires substantial time, effort, and financial resources, and may be subject to both expected and unforeseen delays, and there can be no assurance that any approval will be granted on a timely basis, if at all.

The FDA may decide that our data are insufficient for approval of our products and require additional preclinical, clinical or other studies or additional work related to chemistry, manufacturing and controls. As we develop our products, we periodically discuss with the FDA clinical, regulatory and manufacturing matters, and our views may, at times, differ from those of the FDA. For example, the FDA regulates our products that consist of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's claimed effect. The FDA has maintained questions regarding whether available data and information provided to the FDA demonstrate the contribution of each active ingredient in OMS103. We have not yet reached agreement with the FDA regarding clinical trial design, data analysis, and proposed label claims for OMS103. If we are unable to resolve these questions, we may be required to provide additional information, which may include the results of additional preclinical studies or clinical trials.

If we are required to conduct additional clinical trials or other testing of our products beyond that which we currently contemplate for regulatory approval, if we are unable to complete successfully our clinical trials or other testing, or if the results of these and other trials or tests fail to demonstrate efficacy or raise safety concerns, we may face substantial additional expenses, be delayed in obtaining marketing approval for our products or may never obtain marketing approval.

Even if regulatory approval of a product is obtained, such approval may be subject to significant limitations on the indicated uses for which that product may be marketed, conditions of use, and/or significant post approval obligations, including additional post-marketing studies and clinical trials. These regulatory requirements may, among other things, limit the size of the market for the product. Even after approval, discovery of previously unknown problems with a product, manufacturer, or facility, such as previously undiscovered side effects or adverse effects, may result in restrictions on any product, manufacturer, or facility, including, among other things, a possible withdrawal of approval of the product.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.

We intend to have our products marketed outside the U.S. In order to market our products in the EU and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Although we have filed for regulatory approval of Omidria in the EU, we may be unable to file for regulatory approvals in other non-U.S. geographies and may not receive necessary approvals to commercialize Omidria or any of our other products in any market. The approval procedure varies among countries and can involve additional testing and data review. The requirements governing marketing authorization, the conduct of clinical trials, pricing and reimbursement may vary from country to country. The time required to obtain regulatory approval outside the U.S. and EU may differ from that required to obtain FDA or EMA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA or EMA approval discussed in these "Risk Factors." We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA or EMA does not ensure approval by regulatory agencies in other jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA or EMA. The failure to obtain these approvals could harm our business.

If we are unable to obtain adequate reimbursement from governments or third-party payors for any products that we may develop or if we are unable to obtain acceptable prices for those products, they may not be purchased or used and, as a result, our prospects for revenue and profitability could suffer.

Our future revenue and profit will depend heavily on the availability of adequate reimbursement for the use of our approved products, including Omidria, if approved, from governmental and other third-party payors, both in the U.S. and in other countries. Even if we are successful in bringing one or more products to market, these products may not be considered cost-effective, and the amount reimbursed for any product may be insufficient to allow us to sell the product profitably. Reimbursement by a third-party payor may depend on a number of factors, including the third-party payor's determination that use of a product is:

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

Obtaining reimbursement approval for a product from each government or third-party payor can be a time-consuming and costly process that will require the build-out of a sufficient staff or the engagement of consultants and could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. Because none of our products has been approved for marketing, we can provide no assurances at this time regarding their cost-effectiveness and the amount, if any, or method of reimbursement. Further, we can provide no assurance that the amounts, if any, reimbursed to surgical facilities for utilization of our surgery-related products or to surgeons for the administration and delivery of these products will be considered adequate to justify the use of these products. There may be significant delays in obtaining reimbursement coverage for newly approved products and we may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payor determines that a product is eligible for reimbursement, coverage may be limited to the uses of a product that are either approved by the FDA or foreign regulatory agencies and/or appear in a recognized drug compendium, and other conditions may apply. Increasingly, third-party payors who reimburse healthcare costs, such as government and private payors, are requiring that companies provide them with predetermined discounts from list prices and challenging the prices charged for medical products. Moreover, eligibility for coverage does not mean that any product will be reimbursed at a rate that allows us to make a profit in all cases or at a rate that covers our costs, including research, development, manufacturing, sales and distribution. In non-U.S. jurisdictions, we must obtain separate reimbursement approvals and comply with related foreign legal and regulatory requirements. In some countries, including those in the EU, our products may be subject to government price controls. Pricing negotiations with governmental authorities can take a considerable amount of time and expenditure of resources after the receipt of marketing approval for a product. If the reimbursement that we are able to obtain for any product that we develop is inadequate in light of our development and other costs or is significantly delayed, our business could be materially harmed.

We cannot be certain that OMS103 will receive regulatory approval.

We are redesigning the Phase 3 clinical program evaluating OMS103 in patients undergoing arthroscopic partial meniscectomy to include postoperative pain reduction as the primary endpoint. While OMS103 demonstrated a drug effect in the first Phase 3 clinical trial by reducing early postoperative pain, which was a secondary endpoint, we can provide no assurance that in subsequent trials, OMS103 will meet the primary endpoint of early postoperative pain reduction or that the

design of our Phase 3 program will be acceptable to regulatory authorities. Also, we can provide no assurances that we will have sufficient resources to conduct any subsequent clinical trials that we or regulatory authorities may deem necessary, including any trial regulatory authorities require to show a contribution from each drug in the OMS103 combination. If the data from any subsequent trials are negative or if our program design, data analysis, and proposed label claims are not acceptable to regulatory authorities, we may be unable to seek, or be significantly delayed in seeking, marketing approval of OMS103, which could cause the market price of our common stock to decline significantly.

We may find it difficult to prevent compounders from preparing compounded formulations of products that may compete with our products when commercialized, including Omidria and OMS103.

In November 2013, President Obama signed the Drug Quality and Security Act, which provided for the oversight of compounded human drugs. The law permits a compounding pharmacy to voluntarily register with the FDA as an outsourcing facility and create compounded products, subject to certain requirements including compliance with current good manufacturing practices, or cGMPs, and FDA inspection. Registered outsourcing facilities will be permitted to compound products in large quantities instead of pursuant to individual patient prescriptions. Outsourcing facilities may not engage in wholesale selling of compounded drugs, compound a drug that is essentially a copy of a commercially available drug, or compound drugs that the FDA identifies as prohibited for compounding. Outsourcing facilities will still be subject to potential liability for patent infringement by compounding patented drugs. It is not clear how many compounding pharmacies will register with the FDA as outsourcing facilities or how aggressively the FDA will implement the new law. It is also not clear to what extent traditional compounding pharmacies that do not register as outsourcing facilities will continue to produce compounded drugs without individual patient prescriptions. We may be unable to prevent a registered outsourcing facility or traditional compounding pharmacy from preparing a compounded formulation in large quantities that is similar to Omidria or OMS103 but outside the scope of the claims of our issued patents, or we may be unsuccessful in enforcing our issued patents against outsourcing facilities or traditional compounding pharmacies who prepare compounded formulations that are within the scope of our issued patents. Because these patent violations may be sporadic and dispersed, we may not be able to easily identify the violations. Such actions may hinder our ability to generate enough revenue to achieve profitability and adversely affect our margins.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate product revenue.

Omeros has never sold, marketed or distributed any biopharmaceutical product. Developing an internal sales force is expensive and time-consuming, and a delay in hiring and training an internal sales force could impact the timing or effectiveness of any product launch. Factors that may inhibit our efforts to commercialize any approved products without commercialization partners include:

- our inability to recruit in a timely manner, and retain, adequate numbers of effective sales and marketing personnel, or to partner or contract with a third party to provide sales and marketing services, in the applicable region of the world, particularly before our planned market launch of Omidria, if approved, in the second half of 2014;
- the inability of sales personnel to sell or promote our product(s) to adequate numbers of hospitals, surgery centers, physicians and/or pharmacists;
- our inability to develop and maintain adequate internal information systems to monitor sales by distribution channel, report pricing, maintain customer lists and track selling and marketing operations;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unsuccessful in building a sales and marketing infrastructure or unable to partner with one or more third parties to perform sales and marketing services for our products, we will have difficulty commercializing our products, which would adversely affect our business and financial condition.

In the EU, we plan to enter into partnerships for Omidria marketing and distribution rights with one or more third parties. Outside of the U.S. and EU, we are exploring potential regional partnerships to make Omidria available to ophthalmologists. We have not yet entered into any agreements with third parties to market Omidria outside of the U.S. If we are unable to enter into such agreements on terms acceptable to us, or if we are unable to enter into such agreements at all, we would not expect to see sales of Omidria in those territories, which could adversely affect our business and financial condition.

We have a history of operating losses, and we may not achieve or maintain profitability.

We have not been profitable and have generated substantial operating losses since we were incorporated in June 1994. As of March 31, 2014, we had an accumulated deficit of approximately $271.0 million. We do not anticipate generating revenue from the sale of our products until the second half of 2014 at the earliest and expect to incur additional losses for at least the next several years and cannot be certain that we will ever achieve profitability. As a result, our business is subject to all of the risks inherent in the development of a new business enterprise, such as the risks that we may be unable to obtain additional capital needed to support the preclinical and clinical expenses of development and commercialization of our products, to develop a market for our products, to successfully transition from a company with a research and development focus to a company capable of commercializing products and to attract and retain qualified management as well as technical and scientific staff.

If we are unable to raise additional capital when needed or on acceptable terms, we may be unable to complete the development and commercialization of Omidria or our other products, or continue our other preclinical development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- prepare for the potential commercialization of Omidria;
- continue the clinical development of OMS824 and OMS721;
- continue the development of OMS103 for use in arthroscopic partial meniscectomy surgery;
- continue our development efforts in our GPCR program to advance this program for potential partnering and/or for internal development of products targeting GPCRs;
- scale-up and produce clinical and commercial supplies of products, and conduct clinical studies for our products, including for Omidria, OMS103, OMS824, OMS721, and products being developed in our PDE7 and Plasmin programs;
- continue research and development in all of our programs;
- make principal and interest payments when due under the Oxford/MidCap Loan Agreement;
- initiate and conduct clinical trials for other products;
- make milestone payments to our collaborators;
- undertake development activities and make the required payments to maintain our exclusive licenses to our MASP-2 program; and
- launch and commercialize any products for which we receive regulatory approval.

If we do not raise additional capital through one or more funding avenues (e.g., corporate partnering, debt, equity financings, etc.), we may be unable to commercialize Omidria, if it is approved, or complete all of the clinical trials in our Phase 3 clinical program for OMS103, which could prevent us from generating sales revenue for one or both of those products. Furthermore, we may need to raise additional capital to continue the clinical development of OMS824, OMS721 and our other clinical programs and to advance one or more of our preclinical programs into clinical development. Also, our clinical trials may be delayed or we may need to conduct additional trials for many of the reasons discussed in these “Risk Factors,” which would increase our development expenses and may require us to raise additional capital to complete the clinical development and commercialization of our products and to decrease spending on our other development programs. If we are unable to raise sufficient capital to commercialize Omidria, complete the clinical development of OMS103 or advance the development of one or more of our other programs, our business and prospects could be harmed and our stock price could decline significantly.

If our clinical trials are delayed, we may be unable to develop our products on a timely basis, which will increase our development costs and delay the potential commercialization of our products and the subsequent receipt of revenue from sales, if any.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause regulatory agencies, Institutional Review Boards or Ethics Committees, or us to delay our clinical trials or suspend or delay the analysis of the data from those trials. Clinical trials can be delayed for a variety of reasons, including:

- discussions with the FDA, the EMA or other foreign authorities regarding the scope or design of our clinical trials;
- delays or the inability to obtain required approvals from Institutional Review Boards, Ethics Committees or other responsible entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- lower than anticipated retention rates of patients in clinical trials;

- the need to repeat or conduct additional clinical trials as a result of problems such as inconclusive or negative results, poorly executed testing, a failure of a clinical site to adhere to the clinical protocol or an unacceptable study design;
- an insufficient supply of product materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product materials for FDA and foreign regulatory approval;
- an unfavorable FDA inspection or review of a clinical trial site or records of any clinical investigation;
- the occurrence of unacceptable drug-related side effects or adverse events experienced by participants in our clinical trials; or
- the placement by a regulatory agency of a trial on a clinical hold.

In addition, a clinical trial or development program may be suspended or terminated by us, the FDA or other regulatory authorities, or Institutional Review Boards or Ethics Committees due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial or development program, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards or Ethics Committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial. If the results of our clinical trials are not available when we expect or if we encounter any delay in the analysis of data from our clinical trials, we may be unable to file for regulatory approval or conduct additional clinical trials on the schedule we currently anticipate. Any delays in completing our clinical trials may increase our development costs, would slow down our product development and regulatory submission process, could delay our receipt of product revenue and could make it difficult to raise additional capital. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product. In addition, significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our future products and may harm our business.

If we experience delays or difficulties in enrolling patients in our clinical trials, those clinical trials could take longer than expected to complete and our receipt of regulatory approvals could be delayed or prevented.

We may be unable to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or other regulatory authorities outside the U.S.

Patient enrollment for any of our clinical trials also may be affected by other factors, including:

- the severity of the disease under investigation;
- the design of the trial protocol;
- the size of the patient population;
- the availability of competing therapies and clinical trials;
- the eligibility criteria of the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately before and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays may result in increased development costs for our product candidates, and we may not have or be able to obtain sufficient cash to fund such increased cost when needed, which could result in further delay or termination of the trial.

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

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

We have no capacity to manufacture clinical or commercial supplies of our products and intend to rely solely on third parties to manufacture clinical and commercial supplies of all of our products.

We do not intend to manufacture our products for our clinical trials or on a commercial scale and intend to rely on third parties to do so. With the exception of our agreements with DSM Pharmaceuticals, Inc., or DSM, for the commercial supply of Omidria and Hospira Worldwide, Inc. for the commercial supply of liquid OMS103, we have not yet entered into any agreement for the commercial supply of any of our products, and can provide no assurance that we will be able to do so on commercially reasonable terms, if at all. Our agreement with DSM for the supply of Omidria has a term extending through December 31, 2015, which term could be terminated early by either party upon the occurrence of certain specified events, including any mandate from a regulatory authority prohibiting manufacture at DSM's relevant facility in the absence of an agreement with DSM to transfer the manufacture of Omidria to an alternative DSM facility. If DSM is unable or unwilling to manufacture Omidria at its planned facility, or if our supply agreement with DSM is terminated, we will have to transfer the Omidria manufacturing process to another facility or manufacturer. The cost of transferring the Omidria manufacturing process to an alternate DSM manufacturing facility or a different manufacturer, or any significant delays in the timely completion of the transfer of the Omidria manufacturing process, could materially harm our business and prospects. Any significant delays in the manufacture of clinical or commercial supplies of our other products could materially harm our business and prospects.

If the contract manufacturers that we rely on experience difficulties with manufacturing our products or fail FDA or other regulatory inspections, our clinical trials, regulatory submissions and ability to commercialize our products and generate revenue may be significantly delayed.

Contract manufacturers that we select to manufacture our products for clinical testing or for commercial supply may encounter difficulties with the small- and large-scale formulation and manufacturing processes required for such manufacture. These difficulties could result in delays in clinical trials, regulatory submissions, or commercialization of our products. Once a product is approved and being marketed, these difficulties could also result in the recall or withdrawal of the product from the market or failure to have adequate supplies to meet market demand. Even if we are able to establish additional or replacement manufacturers, identifying these sources and entering into definitive supply agreements and obtaining regulatory approvals may require a substantial amount of time and cost and such supply arrangements may not be available on commercially reasonable terms, if at all.

In addition, we and our contract manufacturers must comply with cGMPs that are strictly enforced by the FDA and other regulatory authorities through facilities inspection programs. These cGMPs include quality control, quality assurance and the maintenance of records and documentation. We or our contract manufacturers may be unable to comply with cGMPs or with other FDA, state, local and foreign regulatory requirements. Although we have obligations to review their compliance, we have limited control over our current, and expect to have limited control for any future, contract manufacturers' compliance with these regulations and standards, or with their quality control and quality assurance procedures. Large-scale manufacturing processes that have been developed, or which would be developed in the future, for our products will require validation studies, which the FDA or other regulatory authorities must review and approve. Failure to comply with these requirements by our contract manufacturers could result in the initiation of enforcement actions by the FDA and other regulatory authorities, as well as the imposition of sanctions, including fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall or withdrawal of product approval. If the safety of any product supplied by contract manufacturers is compromised due to their failure to adhere to applicable laws or for other reasons, we may not be able to

obtain or maintain regulatory approval for or successfully commercialize one or more of our products, which would harm our business and prospects significantly.

If one or more of our contract manufacturers were to encounter any of these difficulties or otherwise fail to comply with its contractual obligations, our ability to provide products to patients in our clinical trials or on a commercial scale would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending on the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely. If we need to change to other commercial manufacturers, the FDA and comparable foreign regulators must first approve these manufacturers' facilities and processes, which could require new testing and compliance inspections, and the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our products.

Ingredients necessary to manufacture our PharmacoSurgery products may not be available on commercially reasonable terms, if at all, which may delay the development and commercialization of our products.

We must purchase from third-party suppliers the active pharmaceutical ingredients necessary for our contract manufacturers to produce our PharmacoSurgery products for our clinical trials and, if approved, for commercial distribution. Suppliers may not sell these ingredients to us at the time we need them or on commercially reasonable terms, if at all. Although we have or intend to enter into agreements with third-party suppliers that will guarantee the availability and timely delivery of active pharmaceutical ingredients for our PharmacoSurgery products, we have not yet entered into agreements for the supply of all such ingredients and we may be unable to secure all such supply agreements or guarantees. Even if we were able to secure such agreements or guarantees, our suppliers may be unable or choose not to provide us the ingredients in a timely manner or in the minimum guaranteed quantities. If we are unable to obtain and then supply these active pharmaceutical ingredients to our contract manufacturers for our clinical trials or for the manufacture of commercial supplies if products, such as Omidria, are approved, potential regulatory approval of our products or, if approved, commercialization of our products, would be delayed, significantly impacting our ability to develop and commercialize our products, which would materially affect our ability to generate revenue from the sale of our products.

We may need licenses for active ingredients from third parties so that we can develop and commercialize some products from some of our current preclinical programs, which could increase our development costs and delay our ability to commercialize products.

Should we decide to use active pharmaceutical ingredients in any of our products that are proprietary to one or more third parties, we would need to obtain licenses to those active ingredients from those third parties. For example, we intend to use proprietary active ingredients that we have exclusively licensed from Daiichi Sankyo Co., Ltd. for our PDE7 program. If we are unable to access rights to these active ingredients prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate products from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these products. If we are unable to access rights to the desired active ingredients on commercially reasonable terms or develop suitable alternate active ingredients, we may not be able to commercialize products from these programs.

Our agreements with Vulcan and the Life Sciences Discovery Fund Authority, a granting agency of the State of Washington, or LSDF, include terms that may reduce the purchase price that a third party would be willing to pay for the GPCR program or for us in a change of control, should we elect to proceed with either of such transactions.

Under our GPCR funding agreement with Vulcan, if we decide to sell or assign all or substantially all of the assets in our GPCR program prior to the time that Vulcan has received $60.0 million from us under our agreement, Vulcan may require that the purchaser assume all of our rights and obligations pursuant to the agreement, including our obligation to pay tiered percentages of any net proceeds that we receive from the GPCR program. The term of the Vulcan agreement is at least 35 years. If, at our option, we elect to assign the LSDF agreement in connection with the sale of the GPCR program, a potential purchaser would also have to assume similar payment obligations to LSDF. Potential purchasers of our GPCR program may be less inclined to purchase the program because of these obligations. Further, even if they are willing to assume our rights and obligations, they may be unwilling to pay as much for our GPCR program as they would be without such requirement. In addition, if a transaction results in a change of control of Omeros, the acquiring party will be required to assume our rights and obligations under the Vulcan and LSDF agreements. As a result of these provisions, a party that wants to acquire us through a change of control may be less inclined to do so or not be willing to pay as much.

We have granted Vulcan a lien on all of our GPCR assets, excluding intellectual property, that provides Vulcan a right, senior to our shareholders, to receive proceeds generated from a liquidation of our GPCR assets as well as potentially limiting our operating and financial flexibility.

We have granted Vulcan a lien on all of our GPCR assets, excluding intellectual property, to secure our obligations under our agreement with Vulcan. This lien is, and will continue to be, junior to security interests we grant to third parties in connection with indebtedness for borrowed money. The lien will automatically be released once we have paid Vulcan or its affiliate $25.0 million out of net proceeds received from the GPCR program. If we default under our agreement with Vulcan, in certain circumstances Vulcan may, subject to the rights of any holders of senior security interests, take control of such pledged assets. We have also agreed with Vulcan not to grant any liens on our GPCR-related intellectual property related to our cellular redistribution assay, subject to specified exceptions. If we are liquidated, Vulcan's right to receive any payments then due under our agreement would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation of our GPCR program assets. Further, the junior lien and negative pledge on our intellectual property restrict our operating and financial flexibility, potentially limiting our ability to pursue business opportunities and making it more difficult for us to respond to changes in our business.

We may not be successful in partnering new drug targets made accessible by our GPCR program.

To fully exploit the developments arising from our GPCR program, we intend to partner or out-license our proprietary rights associated with some of the new drug targets made accessible by our GPCR program. There can be no assurance that we will enter into any such agreements and, even if we do, that the terms of any such agreements will be favorable to us. For example, potential partners may require that we first advance the development and optimization of functionally active compounds identified from our high-throughput screening of orphan GPCRs prior to entering into a licensing or other partnering arrangement, requiring us to invest substantial resources without any certainty that we will successfully optimize one or more of the compounds or recover our investment. Potential partners may also require that we obtain the issuance of patents protecting the new drug targets and compounds that interact with those targets. We may not be successful in obtaining the issuance of such patents for the targets and compounds we intend to partner or for the targets and compounds we intend to develop ourselves and, even if we do, the breadth of our patent rights may be inadequate or may be viewed as inadequate by potential partners. Further, if we are unable to secure the issuance of patents or patents of adequate breadth, we may be unable to exclude competitors from developing and commercializing compounds that interact with GPCR targets, limiting our ability to successfully commercialize these targets either independently or with a partner.

Our ability to pursue the development and commercialization of products from our MASP-2 program depends on the continuation of licenses from third parties.

Our MASP-2 program is based in part on intellectual property rights that we licensed on a worldwide exclusive basis from the University of Leicester, the UK Medical Research Council at Oxford University and Helion. The continued maintenance of these agreements requires us to undertake development activities and, if regulatory approval for marketing is obtained, to pay royalties to each of these organizations upon commercialization of a MASP-2 product, such as OMS721. In addition, we are obligated to pay Helion up to $6.6 million upon the achievement of certain events related to a MASP-2 product, such as the initiation of clinical trials, receipt of marketing approval and reaching specified sales milestones. Our ability to continue development and commercialization of products from our MASP-2 program, including OMS721, depends on our maintaining these exclusive licenses, which cannot be assured.

Our ability to pursue the development and commercialization of products from our MASP-2 and Plasmin programs depends on third-party developers and manufacturers of biologic drug products.

Any product from our MASP-2 or Plasmin programs would be a biologic drug product and we do not have the internal capability to hybridize, clone or manufacture biologics for clinical or commercial use. There are only a limited number of manufacturers of biologic drug products and we cannot be certain that we can enter into supply agreements with them on commercially reasonable terms, if at all. If we are unable to obtain clinical supplies of drug product for one of these programs, clinical trials or the development of any such product for that program could be substantially delayed until we can find and qualify a manufacturer, which may increase our development costs, slow down our product development and approval process, delay receipt of product revenue and make it difficult to raise additional capital.

Our preclinical programs may not produce products that are suitable for clinical trials or that can be successfully commercialized or generate revenue through partnerships.

Any products from our preclinical programs, including our PDE7, Plasmin and GPCR programs, must successfully complete preclinical testing, which may include demonstrating efficacy and the lack of toxicity in established animal models, before entering clinical trials. Many pharmaceutical and biological products do not successfully complete preclinical testing and, even if preclinical testing is successfully completed, may fail in clinical trials. In addition, there can be no assurance that positive results from preclinical studies will be predictive of results obtained from subsequent preclinical studies or clinical trials. For example, our studies of PDE7 inhibitors in different animal models of Parkinson's disease, which may or may not be relevant to the mechanism of action of PDE7 inhibitors in humans, have produced varying results. Further, we cannot be certain

that any of our preclinical product development programs will generate products that are suitable for clinical testing. For example, we have not yet generated any products from our GPCR program. We may discover that there are fewer drugable targets among the orphan GPCRs than we currently estimate and that, for those orphan GPCRs for which we identify functionally active compounds that we elect to develop independently, we are unable to develop related products that successfully complete preclinical or clinical testing. If we are unable to develop products, potential corporate partners may be unwilling to enter into partnership agreements with us. We also cannot be certain that any products that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

Because we have a number of development programs and are considering a variety of products, we may expend our limited resources to pursue a particular product or products and fail to capitalize on products or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we must focus on clinical and preclinical development programs and products that we believe are the most promising. As a result, we may forego or delay the pursuit of opportunities with other products or other indications that later prove to have greater commercial potential and may not be able to progress development programs, including our GPCR program, as rapidly as otherwise possible. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Further, if we do not accurately evaluate the commercial potential or target market for a particular product, we may relinquish valuable rights to that product through collaboration, license or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

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

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

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Case law and policy regarding the breadth of claims allowed in biotechnology patents has continued to evolve in the U.S., and tests used for determining the patentability of patent claims in all technologies are in flux. The pharmaceutical, biotechnology and other life sciences patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. For example, in the U.S., a determination of patentability by the U.S. Patent and Trademark Office, or USPTO, or validity by a court or other trier of fact requires a determination that the claimed invention has utility and is both novel and non-obvious to those of ordinary skill in the art in view of prior known publications and public information, and that the patent specification supporting the claim adequately describes the claimed invention, discloses the best mode known to the inventors for practicing the invention, and discloses the invention in a manner that enables one of ordinary skill in the art to make and use the invention. These standards may be challenging to meet for patents directed to some of our technologies, including our target-based technologies. The ultimate determination by the USPTO or by a court or other trier of fact in the U.S., or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may impact the patentability of claims in our various patent applications and patents, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, our licensed patents or patent applications or in third-party patents.

We cannot assure you that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents, nor can we make assurances as to the scope of any claims that may issue from these pending and future patent applications or to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the U.S. or foreign jurisdictions, which could limit patent protection for our products and materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to make the inventions covered by any of our pending U.S. patent applications filed or having priority dates prior to the U.S. having adopted a first-to-file standard on March 16, 2013, or any U.S. patents issued based on such patent applications;
- we might not have been the first to file patent applications on inventions that are the subject of pending foreign patent applications or that are the subject of pending U.S. patent applications filed or having priority dates after March 16, 2013, or any patents issued based on such foreign or U.S. patent applications;
- others may independently develop similar or alternative technologies or products or duplicate any of our technologies or products;
- we may not be able to generate sufficient data to support fully patent applications that protect the entire breadth of developments expected to result from our development programs, including the GPCR program;
- it is possible that none of our pending patent applications will result in issued patents or, if issued, that these patents will be sufficient to protect our technology or provide us with a basis for commercially viable products or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws;
- if issued, the patents under which we hold rights may not be valid or enforceable; or
- we may develop additional proprietary technologies or products that are not patentable and which are unlikely to be adequately protected through trade secrets if, for example, a competitor were to develop independently duplicative, similar or alternative technologies or products.

In addition, to the extent we are unable to obtain and maintain patent protection for one of our products or in the event such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product for follow-on indications.

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

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe the patents. It may not be feasible to detect and undertake patent enforcement action to stop infringing activity by a number of individual entities, each on a small scale, such as compounding pharmacies.

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

Although we have conducted searches of third-party patents with respect to our programs, we have not obtained written freedom to operate opinions for our programs and may not have identified all relevant third-party patents. Consequently, we cannot assure you that third-party patents containing claims covering our products, programs, technologies or methods do not exist, have not been filed, or could not be filed or issued.

Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents, our licensors' patents, our pending applications or our licensors' pending applications, or that we or our licensors were the first to invent or the first to file patent applications for inventions embodied in our technologies. Our competitors may have filed, and may in the future file, patent applications covering technologies similar to ours. Any such patent application may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If our or our licensors' pending patent applications issue as patents, we can provide you no assurances that the patents will not be challenged in post-grant review or inter-parties review proceedings. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in interference derivation proceedings declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. Similar patent opposition proceedings in other countries and regions may also be costly and could result in the loss of patent rights in those countries and regions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the capital necessary to continue our operations.

The terms of our debt facility place restrictions on our operating and financial flexibility and, if we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

In March 2014, we borrowed $32.0 million pursuant to the terms of the Oxford/MidCap Loan Agreement. As collateral for this loan, we pledged substantially all of our assets other than intellectual property. The Oxford/MidCap Loan Agreement restricts our ability to incur additional indebtedness, pay dividends, pledge our intellectual property and engage in significant business transactions such as a change of control of Omeros, so long as we owe any amounts to the lenders under the Oxford/MidCap Loan Agreement. Any of these restrictions could significantly limit our operating and financial flexibility and ability to respond to changes in our business or competitive activities. In addition, if we default under the Oxford/MidCap Loan Agreement, the lenders may have the right to accelerate all of our repayment obligations under the Oxford/MidCap Loan Agreement and to take control of our pledged assets, which include our cash, cash equivalents and short-term investments, potentially requiring us to renegotiate the Oxford/MidCap Loan Agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. An event of default under the Oxford/MidCap Loan Agreement includes the occurrence of any material adverse effect upon our business operations, properties, assets, results of operations or financial condition, taken as a whole with respect to our viability, that would reasonably be expected to result in our inability to repay the loan. If either lender declares all obligations under the Oxford/MidCap Loan Agreement immediately due and payable upon the occurrence of any event that the lender interprets as constituting an event of default as defined under the Oxford/MidCap Loan Agreement, including but not limited to the lender concluding that a material adverse change has occurred as defined under the Oxford/MidCap Loan Agreement, we will be required to repay the loan immediately or to attempt to reverse the declaration through negotiation or litigation. Any declaration of an event of default could significantly harm our business and prospects and could cause our stock price to decline. If we raise any additional debt financing, the terms of such debt could further restrict our operating and financial flexibility.

We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research operations produce hazardous waste products, which include chemicals and radioactive and biological materials. We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply with applicable legal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. We generally contract with third parties for the disposal of such substances and store our low-level radioactive waste at our facility until the materials are no longer considered radioactive. We may be required to incur further costs to comply with current or future environmental and safety regulations. In addition, although we carry insurance, in the event of accidental contamination or injury from these materials, we could be held liable for any damages that result and any such liability could exceed our insurance coverage and other resources.

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

Our success depends to a significant degree on the continued individual and collective contributions of our management team. The members of our management team are at-will employees, and we do not maintain any key-person life insurance policies other than on the life of Gregory A. Demopulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, could delay the execution of our business strategy, cause us to lose a strategic partner, or otherwise materially affect our operations.

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

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

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

To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to manage effectively the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Additionally, our inability to manage growth effectively could cause our operating costs to grow even faster than we currently are anticipating.

We incur significant costs and demands on management as a result of complying with the laws and regulations affecting public companies.

We have incurred, and will continue to incur, significant costs associated with compliance with public company reporting and corporate governance requirements, including under the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, as well as rules implemented by the SEC and The NASDAQ Stock Market. The requirements of applicable SEC rules and regulations may increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage than was previously available. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

We are required to make an assessment of the effectiveness of our internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Further, our independent registered public accounting firm has been engaged to express an opinion on the effectiveness of our internal control over financial reporting. Section 404 requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting for each fiscal year. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses.

If we are unable to comply with the requirements of Section 404, management may not be able to assess whether our internal control over financial reporting is effective, which may subject us to adverse regulatory consequences and could result in a negative reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we fail to maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner or otherwise comply with the standards applicable to us as a public company. Any failure by us to provide the required financial information in a timely manner could materially and adversely impact our financial condition and the market value of our securities.

Risks Related to Our Industry

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

We may not achieve commercial success, particularly if our competitors market products that are safer, more effective, less expensive or faster to reach market than products or any future products that we may develop. Our competitors also may market a product that proves to be unsafe or ineffective, which may affect the market for our competing product, or future product, regardless of the safety or efficacy of our product. For example, other pharmaceutical companies, many with significantly greater resources than we have, are developing PDE10 inhibitors similar to our product OMS824, and these companies may be further along in development and have the resources to develop their products at a faster rate than we can. For example, in 2012, Pfizer Inc. announced that its PDE10 inhibitor product candidate failed to demonstrate efficacy in a Phase 2 clinical trial evaluating the compound in acute exacerbation of schizophrenia. This and other potential clinical trial failures of PDE10 inhibitor product candidates may negatively reflect on the ability of OMS824 to demonstrate safety and efficacy. In addition, we believe that other companies are attempting to find compounds that functionally interact with orphan GPCRs. If any of these companies are able to achieve this for a given orphan GPCR before we do, we may be unable to establish a commercially valuable intellectual property position around that orphan GPCR. The failure of any product that we may market to effectively compete with products marketed by our competitors would impair our ability to generate revenue, which would have a material adverse effect on our future business, financial condition and results of operations.

The pharmaceutical industry is intensely competitive and many of our competitors have significantly more resources and experience, which may limit our commercial opportunities.

The pharmaceutical industry is intensely competitive in the markets in which we expect to compete. We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. Our competitors may:

- operate larger research and development programs, possess commercial-scale manufacturing operations or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to remain current with rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our product discovery process that we believe we derive from our research approach and proprietary technologies and programs.

Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products if and when any of them are approved.

Any product for which we obtain marketing approval, together with the manufacturing processes, post-approval clinical data, and advertising and promotional activities for such product, will be subject to continued regulation by the FDA and other regulatory agencies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or the approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products or their manufacture, or failure to comply with regulatory requirements, may result in:

- restrictions on such products or manufacturing processes;
- withdrawal of the products from the market;
- voluntary or mandatory recalls;
- fines;
- suspension or withdrawal of regulatory approvals;
- product seizures; or
- injunctions or the imposition of civil or criminal penalties.

If we are slow or unable to adapt to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we may lose marketing approval for our products when and if any of them are approved.

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

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

Risks Related to Our Common Stock

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

During the 12-month period ended March 31, 2014, our stock traded as high as $14.69 per share and as low as $3.65 per share. The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors could include:

- FDA or EMA actions related to our NDA and MAA submissions for Omidria;
- FDA or foreign regulatory actions related to any of our other products;
- results from our clinical development programs, including the data from our ongoing clinical development programs evaluating Omidria, OMS103, OMS824, OMS721 and PPARγ;
- announcements regarding the progress of our preclinical programs, including without limitation our GPCR program;
- failure of any of our products, if approved, to achieve commercial success;
- quarterly variations in our results of operations or those of our competitors;
- our ability to develop and market new and enhanced products on a timely basis;
- announcements by us or our competitors of acquisitions, regulatory approvals, clinical milestones, new products, significant contracts, commercial relationships or capital commitments;
- third-party coverage and reimbursement policies;
- additions or departures of key personnel;
- commencement of, our involvement in and resolution of litigation;
- our ability to meet our repayment and other obligations under the Oxford/MidCap Loan Agreement;
- the inability of our contract manufacturers to provide us with adequate commercial supplies of our products;
- changes in governmental regulations or in the status of our regulatory approvals;
- changes in earnings estimates or recommendations by securities analysts;
- any major change in our board or management;
- general economic conditions and slow or negative growth of our markets; and
- political instability, natural disasters, war and/or events of terrorism.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. Also, from time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the commercialization of our product and products may be delayed.

In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies. Broad market and industry factors may seriously

affect the market price of companies' stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

We expect that we will continue to need additional capital in the future; however, such capital may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing shareholders would experience further dilution.

Although we expect that we will need additional capital in the future, we cannot be certain that it will be available to us on acceptable terms, if at all, when required. Disruptions in the global equity and credit markets may limit our ability to access capital. To the extent that we raise additional funds by issuing equity securities, our shareholders would experience dilution, which may be significant and could cause the market price of our common stock to decline significantly. Any debt financing, if available, may restrict our operations similar to the Oxford/MidCap Loan Agreement, or in other ways. In addition, the underwriting agreement we entered into in connection with our March 2014 public offering prohibits us from issuing our equity securities, subject to certain exceptions, through June 12, 2014 plus up to an additional 18 days in certain circumstances. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or one or more of our other research and development initiatives. We also could be required to seek collaborators for one or more of our current or future products at an earlier stage than otherwise would be desirable or on terms that are less favorable than otherwise might be available or to relinquish or license on unfavorable terms our rights to technologies or products that we otherwise would seek to develop or commercialize ourselves. We also may have insufficient funds or otherwise be unable to advance our preclinical programs, such as potential new drug targets developed from our GPCR program, to a point where they can generate revenue through partnerships, collaborations or other arrangements. Any of these events could significantly harm our business and prospects and could cause our stock price to decline.

Future sales of shares by holders of outstanding warrants and options could cause our stock price to decline.

Approximately 9.5 million shares of common stock that are either subject to outstanding warrants or subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

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

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

Our business requires significant funding, and we have not generated any material revenue. We currently plan to invest all available funds and future earnings, if any, in the development and growth of our business. Additionally, under the Oxford/MidCap Loan Agreement, we have agreed not to pay any dividends so long as we have any outstanding obligations under the agreement. Therefore, we currently do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, a rise in the market price of our common stock, which is uncertain and unpredictable, will be your sole source of potential gain in the foreseeable future, and you should not rely on an investment in our common stock for dividend income.

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ITEM 6. EXHIBITS

Exhibit Number	Description
4.1(1)	Notice Regarding the Extension of the Expiration Date to September 29, 2014 of Warrants to Purchase up to an Aggregate of 197,478 Shares of the Common Stock of Omeros Corporation
10.1(2)	Loan and Security Agreement among Omeros Corporation, Oxford Finance LLC and MidCap Financial SBIC, LP dated March 5, 2014
10.2(2)	Form of Secured Promissory Note issued by the registrant to Oxford Finance LLC dated March 5, 2014
10.3(2)	Form of Secured Promissory Note issued by the registrant to MidCap Financial SBIC, LP dated March 5, 2014
10.4(3)	Underwriting Agreement, dated March 14, 2014, among Omeros Corporation and Cowen and Company, LLC, as representative of the Underwriters
10.5††	Pharmaceutical Manufacturing and Supply Agreement dated March 5, 2014 by and between DSM Pharmaceuticals, Inc. and Omeros Corporation
12.1	Ratio of Earnings to Fixed Charges
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference from the registrant's Current Report on Form 8-K filed on April 3, 2014 (File No. 001-34475).
(2) Incorporated by reference from the registrant's Current Report on Form 8-K filed on March 7, 2014 (File No. 001-34475).
(3) Incorporated by reference from the registrant's Current Report on Form 8-K filed on March 18, 2014 (File No. 001-34475).
†† Portions of this exhibit are redacted in accordance with a request for confidential treatment.

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: May 12, 2014

/s/ Gregory A. Demopulos

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

Dated: May 12, 2014

/s/ Michael A. Jacobsen

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

Exhibit 10.5

CONFIDENTIAL TREATMENT REQUESTED
under 17 C.F.R. § 200.80(b)(4)
and 240.24b-2

PHARMACEUTICAL MANUFACTURING AND SUPPLY AGREEMENT

Dated March 5, 2014

By and Between

DSM PHARMACEUTICALS, INC.
[†]

and

Omeros Corporation
Seattle, WA

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

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PHARMACEUTICAL MANUFACTURING AND SUPPLY AGREEMENT

By and Between
DSM Pharmaceuticals, Inc. and
Omeros Corporation

THIS PHARMACEUTICAL MANUFACTURING AND SUPPLY AGREEMENT (this "Agreement") is made effective as of this 5th day of March, **2014**, (the "Effective Date") by and between **DSM Pharmaceuticals, Inc**., a Delaware corporation with principal place of business at 5900 Martin Luther King Jr. Hwy., Greenville, North Carolina 27834 ("DSM") and **Omeros Corporation,** 201 Elliott Avenue West, Seattle, WA 98119 ("OMEROS"); (each individually a "Party" and collectively the "Parties").

W I T N E S S:

WHEREAS, OMEROS anticipates that it will obtain regulatory approval to market a certain pharmaceutical product in finished dosage form for human use; and

WHEREAS, DSM has the necessary knowledge, professional expertise, facilities, manufacturing authorization, equipment, and trained, competent personnel to manufacture such pharmaceutical product for OMEROS; and

WHEREAS, OMEROS desires to establish DSM as a manufacturer of such pharmaceutical product and DSM desires to perform such services and to manufacture such product for OMEROS, all on the terms and conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the mutual covenants and promises set forth herein, the Parties agree as follows:

ARTICLE 1: DEFINITIONS

The following terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement:

1.1. Acquisition Cost. "Acquisition Cost" shall mean the actual invoiced price paid by either Party to any Third Party (adjusted for any discounts, rebates or refunds realized by the payor Party), including without limitation shipping and handling costs, taxes and customs duties to the extent invoiced, in connection with the acquisition of Active Pharmaceutical Ingredients, Excipients, packaging or other materials utilized in Manufacturing.

1.2. Active Pharmaceutical Ingredients or API. "Active Pharmaceutical Ingredients" or "API" shall mean the active pharmaceutical ingredients for each Product, as set forth in the respective Product Addendum in **ANNEX 1**.

1.3. Affiliate. "Affiliate" shall mean any corporation or non-corporate entity that directly or indirectly controls, is controlled by, or is under common control with a Party. A corporation or non-corporate entity shall be regarded as in control of another corporation if it (a) owns or directly or indirectly controls at least fifty percent (50%) of the voting stock of the other corporation or (b) has the power to direct or cause the direction of the management and policies of such corporation or non-corporate entity.

1.4. Agreed Additional Compliance Regions. "Agreed Additional Compliance Regions" shall mean any countries or regions outside of the Territory for which DSM and OMEROS agree in a Product Addendum that Product shall be Manufactured in accordance with Applicable Law in such countries or regions.

1.5. Agreement. "Agreement" shall have the meaning set forth in the preamble.

1.6. API Certificate of Analysis. "API Certificate of Analysis" shall mean a document that sets forth the analytical tests, associated acceptance criteria and test results for each shipment of API supplied to DSM by OMEROS pursuant to this Agreement, in accordance with the API Specifications, and states whether such API meets the API Specifications and is manufactured in accordance with Applicable Pharmaceutical Law.

1.7. API Specifications. "API Specifications" shall mean the specifications for the API set forth in the respective Product Addendum in **ANNEX 1**, as determined in accordance with the analytical methodology related thereto, and may be updated from time to time in accordance with Section 5.6.1.

1.8. Applicable Law. "Applicable Law" shall mean all applicable laws, rules and regulations, including any applicable rules, regulations, guidelines, or other requirements of Governmental Authorities in the Territory and in any Agreed Additional Compliance Regions that may be in effect from time to time, including, without limitation, Applicable Pharmaceutical Law and the United States Foreign Corrupt Practices Act.

1.9. Applicable Pharmaceutical Law. "Applicable Pharmaceutical Law" shall mean all applicable laws, rules and regulations, including any applicable guidelines, or other

requirements of Regulatory Authorities in the Territory and in any Agreed Additional Compliance Regions, that may be in effect from time to time and that are applicable to pharmaceutical products for human use and the manufacturing and commercialization thereof in the Territory and in any Agreed Additional Compliance Regions, including as applicable and without limitation (a) the FD&C Act as amended; (b) cGMP; (c) guidances promulgated or adopted by the FDA; and (d) ICH guidances; provided, however, that as used in this Agreement the term "Applicable Pharmaceutical Law" as it applies to DSM shall exclusively relate to provisions of the forgoing or any other laws, guidances, or regulations referenced in this Section 1.9 as they apply to pharmaceutical Manufacturing activities. The Parties agree that if a Product Addendum specifies Europe or the European Union as an Agreed Additional Compliance Region then Applicable Pharmaceutical Law for Manufacturing pursuant to such Product Addendum shall also include (e) Regulation (EC) No. 726/2004, Directive 2001/83/EC and national implementations thereof, each as amended from time to time, (f) guidances promulgated or adopted by the European Commission and the European Medicines Agency, including within limitation those compiled in The Rules Governing Medicinal Products in the European Union; (g) legislation, rules and guidances compiled in The Rules Governing Medicinal Products in the European Union or otherwise adopted, promulgated or enforced by the European Medicines Agency; and (h) legislation, rules and guidances promulgated, adopted or enforced by the relevant Regulatory Authorities in the member states of the European Union (as constituted from time to time). The Parties also agree that if a Product Addendum specifies Japan as an Agreed Additional Compliance Region then Applicable Pharmaceutical Law for Manufacturing pursuant to such Product Addendum shall also include (i) legislation, rules and guidances promulgated, adopted or enforced by the Japanese Ministry of Health, Labour, and Welfare, including through its Pharmaceutical and Food Safety Bureau, Health Policy Bureau and Pharmaceuticals and Medical Devices Evaluation Center.

1.10. Approved Vendors. "Approved Vendors" shall mean those vendors listed in **ANNEX** 6, as well as any other vendor that the Parties agree in writing shall be an Approved Vendor or that is deemed an Approved Vendor pursuant to Section 4.4. For purposes of clarity, DSM agrees that all vendors approved by DSM prior to the Effective Date for the supply of an API or an Excipient that is used in Product shall be listed in ANNEX 6 and all vendors approved by DSM after the Effective Date, for reasons other than at OMEROS' request, for the supply of an API or an Excipient that is used in Product shall be added to ANNEX 6 by amendment at OMEROS' request and without cost.

1.11. Auditors. "Auditors" shall have the meaning set forth in Section 10.6.4.

1.12. Batch. "Batch" shall mean any of the following Manufactured by DSM: (a) a cGMP compliant development/clinical trial batch of Product; (b) a Validation Batch; or (c) with respect to Commercial Product, such batch as mutually agreed upon by the Parties and described in **ANNEX 1**.

1.13. Cancelled Production Fee. "Cancelled Production Fee" shall mean, with respect to the cancellation of any (a) monthly requirement for a month in a Firm Purchase Commitment or (b) Purchase Order, a fee of (i) [†] of the applicable Product Price for the cancelled quantity of Product if cancellation occurs more than [†] days prior to the Delivery Date specified in such Purchase Order or in the Firm Purchase Commitment,

as the case may be, (ii) [†] of the applicable Product Price for the cancelled quantity of Product if cancellation occurs between [†] and [†] days prior to such date, (iii) [†] of the applicable Product Price for the cancelled quantity of Product if cancellation occurs between [†] and [†] days prior to such date, and (iv) [†] of the applicable Product Price for the cancelled quantity of Product if cancellation occurs less than [†] days prior to such date. Except in the event of cancelled production runs due to Unapproved Vendor problems as set forth in Section 4.4.3 or as otherwise provided herein, OMEROS shall provide DSM with written notice of any cancellation hereunder and the date of such notice shall be the basis for evaluating the foregoing timeframes. In any situation that OMEROS is obligated to pay a Cancelled Production Fee in accordance with the terms of this Agreement, DSM shall use commercially reasonable efforts to identify substitute commercial uses for the manufacturing capacity made available as a result of Omeros' cancellation, and to the extent that DSM is able to utilize such manufacturing capacity for a Third Party, the Cancelled Production Fee shall be reduced by a credit or refund, as applicable, equal to [†] of the amount of the revenues that DSM receives from the utilization of such capacity; however, in no event shall the Cancelled Production Fee be reduced by any amount greater than [†] of the Cancelled Production Fee prior to application of such credit or refund. For example, the Cancelled Production Fee associated with a cancellation notice received by DSM between [†] and [†] days prior to a specified Delivery Date may be reduced from [†] to [†] by application of such credit, but no lower.

1.14. cGMP. "cGMP" shall mean current Good Manufacturing Practices specified in the FD&C Act and other FDA rules, regulations (other than health authority regulations) and directives including, without limitation, as set forth at 21 CFR Parts 210-211, as well as policies, guidelines and guidances promulgated or adopted by FDA and in effect from time to time governing the manufacture, testing and quality control of investigational drugs, as well as the "Rules Governing Medicinal Products in the European Community," Volume IV, "Guide to good manufacturing practice for medicinal products", and ICH guidelines Q1, Q3, Q7 and Q8, as applicable, as well as the requirements of any applicable international, national, state and local guidelines in the Territory and any Agreed Additional Compliance Region. In the event of a conflict in cGMPs, the U.S. Code of Federal Regulations shall apply.

1.15. Commercial Product. "Commercial Product" shall mean Product supplied hereunder intended for commercial sale.

1.16. *[Intentionally Omitted]*

1.17. Controlled Documents. "Controlled Documents" shall mean the master batch record, SOPs and other quality-controlled documents applicable or referenced for the Manufacture of Product.

1.18. Coordinators. "Coordinators" shall have the meaning set forth in Section 3.1.

1.19. Contract Year. "Contract Year" shall mean each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31 except that the first Contract Year of the Term shall commence on the Effective Date and end on

December 31, 2014, and the last Contract Year of the term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.20. Delivery Date. "Delivery Date" shall mean a date for which delivery of Product is stated in a Purchase Order.

1.21. Developed Intellectual Property. "Developed Intellectual Property" shall mean all inventions, modifications, discoveries, improvements, methods, processes, techniques, documentation, scientific and technical data, drawings and other information (whether patentable or not) that is first conceived, created, reduced to practice, developed or authored in connection with the performance of this Agreement by or on behalf of a Party hereunder, or jointly by or on behalf of the Parties hereunder.

1.22. Development Product. "Development Product" shall mean Product intended for development activities and not intended for commercial sale.

1.23. DSM Intellectual Work Product. "DSM Intellectual Work Product" shall have the meaning set forth in Section 16.4.1.

1.24. DSM Intellectual Property. "DSM Intellectual Property" shall mean all inventions, discoveries, technology, trade secrets, trademarks, copyrights, methods, documentation, scientific and technical data, know-how and other information (including DSM patent rights) that DSM owns or otherwise has a right to use as of the Effective Date or at any time thereafter.

1.25. Effective Date. "Effective Date" shall have the meaning set forth in the preamble.

1.26. Excipients. "Excipients" shall mean the raw materials, other than Active Pharmaceutical Ingredients and packaging, required to manufacture each Product in accordance with the Product Specifications, as such Excipients are listed in the Product Addendum in **ANNEX 1** for each Product to be manufactured hereunder, including the specifications and the analytical methodology related thereto, as such specifications may be amended from time to time in accordance with Section 5.6.1.

1.27. FD&C Act. "FD&C Act" shall mean the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.28. FDA. "FDA" shall mean the United States Food and Drug Administration, or any successor entity.

1.29. Firm Purchase Commitment. "Firm Purchase Commitment" shall mean the obligation of DSM to supply and of OMEROS to purchase, the quantities forecasted by OMEROS in accordance with Section 6.3.

1.30. First Commercial Sale. "First Commercial Sale" shall mean the first commercial sale of a Commercial Product by OMEROS or its Affiliates in the Territory following grant of the Product Approval for such Commercial Product.

1.31. Governmental Authority. "Governmental Authority" shall mean any applicable supranational, federal, national, regional, state, provincial, or local governmental or Regulatory Authority, agency, department, bureau, commission, council, or other entities in the Territory regulating or otherwise exercising authority with respect to the activities contemplated in this Agreement.

1.32. ICH. "ICH" shall mean the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.33. Independent Auditor. "Independent Auditor" shall have the meaning set forth in Section 8.5.

1.34. Initial Term. "Initial Term" shall have the meaning set forth in Section 11.1.

1.35. Intellectual Work Product. "Intellectual Work Product" shall mean the Developed Intellectual Property, the Project Materials, assays, formulations, methods, and all other information, data, writings, and documents first authored or developed in the performance of this Agreement by or on behalf of any Party hereunder, or jointly by or on behalf of the Parties hereunder.

1.36. Latent API Defect. "Latent API Defect" shall mean a defect in any API supplied to DSM by OMEROS existing at the time of delivery to DSM, which defect was not, and could not reasonably have been, discovered in the course of inspection and testing by DSM in conformity with cGMP and applicable SOPs and Controlled Documents, that later causes the API to fail to meet the API Specifications that were in effect at the time of delivery or otherwise makes the API unsuitable for inclusion in the Product.

1.37. Latent Product Defect. "Latent Product Defect" shall mean a defect in any Product supplied to OMEROS pursuant to this Agreement existing at the time of delivery thereof to OMEROS or its designee, which defect was not, and could not reasonably have been, discovered in the course of inspection and release testing by OMEROS or its designee (including, if applicable, DSM) in conformity with cGMP and applicable SOPs and Controlled Documents, that later causes the Product to fail to meet the Product Specifications that were in effect at the time of delivery or otherwise makes the Product unsuitable for its intended use.

1.38. Long Term Forecast. "Long Term Forecast" shall have the meaning set forth in Section 6.1.

1.39. Manufacture and Manufacturing. "Manufacture" and "Manufacturing" shall mean the sourcing and storage of raw materials and components, manufacturing, processing, purifying, formulating, finishing, packaging, labeling, holding, handling, storing, preparing for shipment, inspecting and quality control and stability testing of a Product or compound under this Agreement.

1.40. Manufacturing Improvements. "Manufacturing Improvements" shall have the meaning set forth in Section 5.9.1.

1.41. Monthly Forecast. "Monthly Forecast" shall have the meaning set forth in Section 6.2.

1.42. NDA or ANDA. "NDA" shall mean New Drug Application for the Product, as filed with the FDA; "ANDA" shall mean the Abbreviated New Drug Application for the Product, as filed with the FDA.

1.43. OMEROS Audit. "OMEROS Audit" shall have the meaning set forth in Section 10.6.2.

1.44. OMEROS Intellectual Work Product. "OMEROS Intellectual Work Product" shall have the meaning set forth in Section 16.4.2.

1.45. OMEROS Intellectual Property. "OMEROS Intellectual Property" shall mean all inventions, discoveries, technology, trade secrets, trademarks, copyrights, methods, documentation, scientific and technical data, know-how and other information (including OMEROS patent rights) that OMEROS owns or otherwise has a right to use as of the Effective Date or at any time thereafter.

1.46. OMEROS Regulatory Documentation. "OMEROS Regulatory Documentation" shall mean such documentation as OMEROS has filed or will file with Regulatory Authorities in the Territory relating to the Product prior to or during the Term, including without limitation any NDA, ANDA or analogous filing and the drug product sections as defined in the FDA Common Technical Document and the analogous sections in filings in other territories.

1.47. Packaging Specifications. "Packaging Specifications" shall mean the packaging and labeling specifications for the Product attached hereto in **ANNEX 1**, as such specifications may be amended from time to time by mutual agreement of the Parties.

1.48. Party. "Party" or "Parties" shall have the meaning set forth in the preamble.

1.49. Pre-Existing IPR. "Pre-Existing IPR" shall have the meaning set forth in Section 16.1.

1.50. Product. "Product" shall mean a product that DSM agrees to Manufacture, and OMEROS agrees to purchase hereunder, as more fully described in a Product Addendum attached to **ANNEX 1**.

1.51. Product Addendum. "Product Addendum" shall mean each product addendum attached to **ANNEX 1**, describing each Product to be Manufactured and supplied hereunder, and including further information as provided in Section 2.2.

1.52. Product Approval. "Product Approval" shall mean final approval by FDA of OMEROS' NDA or ANDA for marketing of Product or analogous approval(s) from other Regulatory Authorities, as applicable.

1.53. Product Certificate of Analysis. "Product Certificate of Analysis" shall mean a document that sets forth the analytical tests, associated acceptance criteria and test results for each Batch of Product shipped to OMEROS or its designee pursuant to this Agreement, in accordance with the Product Specifications, and states whether such Product meets

the Product Specifications and is Manufactured in accordance with Applicable Pharmaceutical Law.

1.54. Product Price. "Product Price" shall mean the Commercial Product price set forth in **ANNEX 1**, as such price may be amended from time to time in accordance with this Agreement.

1.55. Product Specifications. "Product Specifications" shall mean the specifications for the Product set forth in **ANNEX 1**, as determined in accordance with the analytical methodology agreed upon by the Parties, and as such specifications may be amended from time to time by mutual agreement of the Parties.

1.56. Project Materials. "Project Materials" shall mean all protocols, reports, documentation, records and data first generated by or on behalf of DSM or OMEROS in the performance of this Agreement, including but not limited to copies of all notebook pages, analytical results, data and memoranda created and or delivered hereunder.

1.57. Purchase Order. "Purchase Order" shall have the meaning set forth in Section 7.1.

1.58. Quality Agreement. "Quality Agreement" shall mean the Quality Agreement in the form of **ANNEX 3** hereto, as may be amended from time to time by the mutual agreement of the Parties.

1.59. Regulatory Authority. "Regulatory Authority" shall mean the Governmental Authorities responsible for regulating any aspect of the development, manufacture, market approval, sale, distribution, packaging or use of any Product within the Territory.

1.60. Requirements Obligation. "Requirements Obligation" shall have the meaning set forth in Section 2.1.

1.61. SKU. "SKU" shall refer, on a Product-by-Product basis, to individual stock keeping units of each Product.

1.62. Specifications. "Specifications" shall mean the Product Specifications and the Packaging Specifications.

1.63. Standard Operating Procedures or SOPs. "Standard Operating Procedures" or "SOPs" shall mean the standard operating procedures and test methods of a Party in force from time to time which define such Party's standard procedures and methods of performing activities applicable to Manufacturing, including without limitation inspection, release testing and acceptance testing.

1.64. Technology Transfer. "Technology Transfer" shall have the meaning set forth in Section 12.1.

1.65. Term. "Term" shall mean the Initial Term and any mutually agreed extensions thereof.

1.66. Territory. "Territory" shall mean the United States of America and its territories and possessions.

1.67. Third Party. "Third Party" or "Third Parties" shall mean any Party other than OMEROS, DSM and their respective Affiliates.

1.68. Unapproved Vendors. "Unapproved Vendors" shall have the meaning set forth in Section 4.4.

1.69. Unit. "Unit" shall mean a unit of Product as defined in the Product Addendum for such Product.

1.70. Validation Activities. "Validation Activities" shall mean those activities to be performed by DSM according to validation protocols prior to the First Commercial Sale including, but not limited to, process qualification of content uniformity, validation of analytical methods, preparation of validation technical reports, cleaning validation, manufacturing and testing of Validation Batches.

1.71. Validation Batches. "Validation Batches" for a dosage form shall mean the initial number of batches Manufactured in support of an NDA or ANDA, which shall be at least three (3) batches, and such additional batches as mutually agreed by the Parties that are manufactured by DSM during the course of the Validation Activities.

ARTICLE 2: SALE AND PURCHASE OF PRODUCT

2.1. Agreement to Purchase and Sell. DSM agrees to Manufacture and sell to OMEROS, and OMEROS agrees to purchase from DSM, (a) the Validation Batches and any other development/clinical trial Batches as set forth in the applicable statement of work attached to **ANNEX 5** and (b) during each Contract Year throughout the Term of this Agreement, at least [†] of OMEROS' requirements of Commercial Product for sale and/or distribution within the Territory in such Contract Year (the "Requirements Obligation"), in accordance with the terms and subject to the conditions of this Agreement. The Parties acknowledge that Validation Batches [†] have already been Manufactured and associated Validation Activities have already been performed under a Memorandum of Agreement for Pharmaceutical Development/Transfer Services by and between the Parties dated June 29, 2012 (hereinafter, the "MOA"); and hereby agree that such Validation Batches shall be subject to the terms and conditions of this Agreement rather than the terms of the MOA and the terms of this Agreement shall be deemed to supersede the terms of the MOA solely with respect to such Validation Batches and associated Validation Activities. Except for the Validation Batches and associated Validation Activities specifically referenced in this Section 2.1, all other services that have already been performed or have been agreed to under the MOA as of the Effective Date of this Agreement shall remain subject to the MOA.

2.2. Product Addenda. Each Product Addendum attached to **ANNEX 1** shall include or clearly reference for the relevant Product (a) the Product Specifications, (b) the Active Pharmaceutical Ingredients and specifications thereof; (c) the Excipients and specifications thereof; (d) the Packaging Specifications; (e) the Product Price and any specific price increase provisions; (f) any special equipment required to be purchased in order to Manufacture the Product pursuant to Section 4.1; (g) lead times for Purchase

Orders and inventories; (h) any special requirements for the procurement of API and/or Excipients; and (i) any Agreed Additional Compliance Regions.

2.3. Development. DSM agrees to perform development activities related to the Product and Manufacture and supply Development Product as requested by OMEROS in accordance with the prices, payment schedule, Delivery Dates, lead times, quantities and other specifications set forth in mutually agreed upon statements of work to be attached to **ANNEX 5**, as such statements of work may be amended from time to time by the mutual agreement of the Parties. For the supply of Development Product, DSM shall not be responsible for any loss of API except (i) in the case of DSM's gross negligence or willful misconduct, (ii) as provided for in Section 4.2.3 or (iii) for the replacement of any defective API from an Approved Vendor that may be supplied by DSM in accordance with Section 4.2.1.

2.4. Disclosure/Development of Health Risk Data. OMEROS agrees to disclose to DSM any information of which OMEROS has knowledge regarding health risks that may be involved in Manufacturing each Product, including information regarding the specified API, Excipients, and other components. Such information shall include, without limitation, Occupational Safety & Health Administration required information, information regarding occupational exposure limits, toxicology studies and reports, and other health-related data. If such data is not available, DSM and OMEROS will cooperate to develop necessary and reasonable data as mutually agreed.

2.5. Customs Requirements.

2.5.1. U.S. Customs Requirements. For Active Pharmaceutical Ingredients, Excipients, and/or other components supplied to DSM by or on behalf of OMEROS that will be imported or exported prior to delivery to DSM, OMEROS agrees that all vendors and carriers responsible for such import or export shall comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism.

2.5.2. Customs Documentation and Valuations. In the event that OMEROS shall export (or cause to be exported) any samples, documentation or Product supplied by DSM under this Agreement, OMEROS shall be responsible for arranging customs documentation and valuations directly or indirectly through its designated customs broker. If OMEROS requests DSM to assume these responsibilities, DSM shall utilize its designated customs broker and shall state customs valuations which appropriately reflect actual contract costs. DSM's reasonable costs in providing such customs services shall be invoiced to, and reimbursed by OMEROS. OMEROS shall be responsible for payment of all customs duties and related assessments.

ARTICLE 3: COORDINATORS

3.1. Appointment of Coordinators. Within ten (10) days after the Effective Date, OMEROS and DSM shall each appoint an authorized representative and a backup representative ("Coordinators") for the exchange of all communications, other than legal notices, related to the Manufacturing. Each Party shall provide notice to the other Party as to the name

and title of the individuals so appointed. Each Party may replace its Coordinators at any time for any reason by providing written notice to the other Party in accordance with Section 21.11.

ARTICLE 4: EQUIPMENT; API; EXCIPIENTS; ARTWORK

4.1. Equipment.

4.1.1. Equipment owned by DSM and located at DSM's [†] facility, shall not be dedicated to any single customer, but shall be available for Manufacturing according to DSM's manufacturing processes requirements and as needed in order to perform DSM's obligations hereunder.

4.1.2. DSM shall be responsible for installing and qualifying and maintaining at its facility, in accordance with Applicable Pharmaceutical Law, any and all new or used equipment, molds, and tooling to be used in the Manufacturing.

4.1.3. OMEROS and DSM shall mutually agree on the terms and conditions for purchase of any special equipment required to be purchased for Manufacturing. Special equipment that OMEROS has agreed to purchase, and for which it shall be financially responsible as to capital modifications, ("Special Equipment") is identified in **ANNEX 2** and such Special Equipment shall be dedicated to Manufacturing. OMEROS may at times authorize DSM, with DSM's approval, to select and order Special Equipment that will be invoiced directly to OMEROS.

4.1.4. DSM shall obtain OMEROS' prior written approval of all costs and expenses associated with the installation and qualification (including without limitation labor and engineering costs) of Special Equipment and OMEROS shall reimburse DSM for all such costs, to the extent approved and reasonable, within thirty (30) days of receiving DSM's invoice(s) relating to such installation and qualification following the completion thereof by DSM.

4.1.5. Title to all Special Equipment, molds and tooling paid for by OMEROS shall be held by OMEROS, provided that all such Special Equipment, molds and tooling shall remain at DSM's facility solely for use in Manufacturing for OMEROS by DSM until the earlier of (a) the expiration or termination of this Agreement or (b) the time at which such Special Equipment is no longer necessary for Manufacturing, after which such Special Equipment shall be transferred to OMEROS or its designee or disposed of, as directed by OMEROS, in each case at OMEROS' reasonable expense. Notwithstanding the foregoing, upon the occurrence of (a) or (b) herein, DSM shall have the option to purchase the Special Equipment from OMEROS by paying OMEROS the book value thereof as depreciated on a straight-line basis based on average years of useable life as provided in Section 11.7.3.

4.1.6. DSM shall be responsible for routine maintenance and servicing of the Special Equipment for so long as the Special Equipment remains at DSM's facility. OMEROS shall be responsible for the cost of non-routine maintenance and non-routine servicing of the Special Equipment (such as major repairs and parts replacement). DSM shall obtain OMEROS' prior written approval for all non-routine maintenance and non-routine

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servicing and the costs and expenses related thereto. OMEROS shall reimburse DSM for all such costs, to the extent approved by OMEROS, within thirty (30) days of receiving DSM's invoice(s) relating to such non-routine maintenance and non-routine servicing.

4.2. Active Pharmaceutical Ingredients and Excipients Supply.

4.2.1. Supply of API, Excipients. OMEROS shall, at its sole discretion and as specified in Section 3 of **Annex 1** (which Section may be amended from time to time by OMEROS upon at least ninety (90) days' prior written notice to DSM), either (a) supply DSM with API meeting the API Specifications in accordance with this Section 4.2, or (b) require DSM to procure such API at OMEROS' cost from vendors approved by OMEROS (which may be, but need not be, Approved Vendors or which may become Approved Vendors through qualification by DSM, at OMEROS' cost in accordance with Section 4.4). For each shipment of API supplied hereunder by OMEROS, OMEROS or its supplier shall provide DSM with an API Certificate of Analysis. DSM shall (i) perform identification, bacterial endotoxin and microbial limit testing on the API, including complete analysis to confirm compliance with the API Specifications for API intended for use in Manufacturing, and confirm the shipment quantity, as well as any other acceptance testing as may be reasonably requested by Omeros, and (ii) notify OMEROS of any inaccuracies with respect to quantity, any failure of any portion of the shipment to meet the acceptance testing reasonably requested by OMEROS, or of any claim that any portion of the shipment does not meet the applicable API Specifications, which testing and notification will, if requested by Omeros following delivery of the API, be completed within [†] days of such request. DSM's use of the API or failure to provide the foregoing notice if requested by OMEROS within the foregoing [†] day time period (or, in the case of a Latent API Defect, promptly after the discovery thereof and in any event no later than the established shelf life of the API) shall be deemed acceptance of such API as conforming. In the event DSM notifies OMEROS of any deficiency in quantity of API supplied by OMEROS, including deficiencies resulting from non-conforming API, OMEROS shall use commercially reasonable efforts to promptly ship to DSM, at OMEROS' expense, the quantity of API necessary to satisfy the shortfall within a sufficient period of time in advance of DSM's scheduled production, unless DSM and OMEROS mutually agree to a reduction in Product quantity to be Manufactured in accordance with Section 7.1.2. Further, in the event that there are any deficiencies in the API supplied by OMEROS hereunder, the provisions of Section 4.4 shall apply equally to OMEROS if and to the extent they apply to Unapproved Vendors.

DSM will supply Excipients and all other materials required for Manufacturing; and such Excipients and other materials shall meet the specifications set forth in the applicable Product Addendum.

4.2.2. Title to API. OMEROS shall retain all rights, title and interest in and to Active Pharmaceutical Ingredients (and any other materials) supplied to DSM by OMEROS hereunder.

4.2.3. Storage and Handling of API. After its delivery to DSM and for the period necessary to timely Manufacture and release the Product, DSM shall bear all responsibility for the safekeeping, storage and handling of API (and any other materials), whether such API is supplied by OMEROS or a Third Party, and shall bear the risk of loss thereof. Such

API shall be labeled and stored in accordance with the API Specifications applicable to such API. During the period set forth herein and subject to Sections 4.2.7 and 5.5, DSM shall promptly reimburse OMEROS for any API supplied or paid for by OMEROS pursuant to Section 4.2.1 that is lost or damaged, at the [†].

4.2.4. Timely Delivery of API. Other than for API that DSM may procure in accordance with Section 4.2.1, OMEROS agrees to supply API to DSM on a timely basis in accordance with lead times as set forth in **ANNEX 1**, so as to enable DSM to receive, inspect, and prepare such API for production according to the schedule reasonably established by DSM in accordance with the terms of this Agreement. OMEROS shall be responsible for any production delays resulting from OMEROS' failure to timely supply conforming API.

4.2.5. Reimbursement of Costs. OMEROS agrees to reimburse DSM for reasonable costs incurred by DSM in decontaminating its production facilities as a result of contamination caused by OMEROS' API stored or used by DSM according to the Controlled Documents or SOPs pertaining to the Product. Notwithstanding the foregoing, in no event shall OMEROS be required to reimburse DSM for such costs where the contamination giving rise to such costs arose from or related to the negligence or willful misconduct of DSM.

4.2.6. Latent Defects in API. OMEROS shall be responsible for all rejected Batches and recall expenses arising from Latent API Defects in API supplied by OMEROS or an Unapproved Vendor.

4.2.7. Consumption/Loss of API.

4.2.7.1. For all Batches other than Validation Batches, the expected yield shall equal the [†] of (a) [†] or (b) [†] (collectively, "Expected Yield").

4.2.7.2. The actual yield of finished Product shall be determined on an annual basis as the average consumption of API per unit of finished Product for all batches produced during the Contract Year. On an annual basis, DSM shall credit OMEROS for the Acquisition Cost of the quantity of API equal to the difference between the amount of API actually used in Manufacturing such Batch and the amount of API that would have been used if the actual yield for the delivered Product had been the Expected Yield [†], subject to any caps on liability set forth in this Agreement. In no event shall the Acquisition Cost of the API exceed [†].

4.3. Artwork. At least (a) one hundred and twenty (120) days prior to the first Delivery Date of any Product for which DSM requires new or modified artwork, OMEROS shall provide, at no cost to DSM, final, camera-ready artwork for all packaging components to be used in the Manufacturing thereof, which artwork shall meet the relevant Packaging Specifications. For the avoidance of doubt, the Parties acknowledge and agree that OMEROS shall be responsible for complying with any and all regulatory requirements relating to the labeling of the Product unless otherwise expressly agreed in a Product Addendum.

4.4. Vendors Designated or Contracted by OMEROS. If OMEROS elects, at its sole discretion, to require DSM to procure Excipients or API from vendors designated by

OMEROS that are not Approved Vendors, then (i) OMEROS shall so advise DSM in writing, (ii) the Parties shall discuss such proposed vendor; and (iii) DSM, within its sole discretion, shall determine whether such proposed vendor (x) shall be considered an Approved Vendor for purposes of this Agreement without additional cost to OMEROS or, (y) upon request by OMEROS and with the consent of DSM, which consent shall not be unreasonably withheld, DSM shall qualify any such proposed vendor, at OMEROS' reasonable cost, so as to render such vendor an Approved Vendor; provided, however, OMEROS shall not be charged for qualification of a vendor if the vendor will also supply API or Excipient for another customer of DSM or for DSM's own use. Any vendor approved by DSM pursuant to this Section 4.4 shall be considered an "Approved Vendor" and shall be added to ANNEX 6. Any vendor proposed by OMEROS that is not an Approved Vendor shall be considered an "Unapproved Vendor" unless and until such vendor becomes an Approved Vendor pursuant to this Section 4.4. DSM shall establish supply arrangements with both Approved Vendors and Unapproved Vendors for Excipients and, if DSM is required to supply API in accordance with the provisions of Section 4.2.1, for API, as applicable, and shall use its reasonable commercial efforts to require that such Approved Vendors not already under contract with DSM or Unapproved Vendors enter into a supply contract directly with DSM; otherwise, OMEROS shall be responsible for the supply of Excipients or API to DSM. In addition, the following provisions shall apply for the use of any Unapproved Vendor:

4.4.1 Cooperation on Supply Problems. DSM shall promptly advise OMEROS if it encounters supply problems, including delays and/or delivery of non-conforming products from Unapproved Vendors, and DSM and OMEROS shall cooperate to reduce or eliminate any supply problems with such Unapproved Vendors.

4.4.2 Annual Certification. OMEROS shall be obligated to certify Unapproved Vendors, as specified in the Quality Agreement, on an annual basis, at its expense, and shall annually supply certification to DSM for such Unapproved Vendors. If DSM is required to certify such Unapproved Vendors, DSM's reasonable certification expenses shall be reimbursed by OMEROS.

4.4.3 Cancelled Production Runs. If a scheduled production run is required to be cancelled as a direct result of an Unapproved Vendor's failure to supply conforming Excipients or API on a timely basis or OMEROS' failure to provide conforming API on a timely basis and to deliver any shortfall to DSM in accordance with Section 4.2.1 if OMEROS is the party supplying the API pursuant to such section, OMEROS shall be obligated to pay DSM the applicable Cancelled Production Fee. Upon OMEROS' payment of the Cancelled Production Fee, the cancelled quantities shall be credited against the Requirements Obligation and be deducted from the Firm Purchase Commitment in proportion to the percentage of the Product Price for the cancelled quantity of Product paid.

4.4.4 Failed Batches. If any Batch fails because of a defect in API or Excipients supplied by OMEROS or an Unapproved Vendor that was not and could not reasonably have been detected by DSM by inspecting and testing as provided for in Section 4.2.1 herein, then OMEROS shall be obligated to pay DSM a fee equal to [†] of the Product Price of the quantities that would have been produced in the failed Batch (based on the Expected Yield) but for the non-conformities in the API or Excipients. Upon OMEROS' payment of such fee, the quantities

that would have been produced shall be deducted from the Firm Purchase Commitment and credited against the Requirements Obligation.

4.4.5 Rescheduled Runs. DSM shall not be obligated to re-schedule any production run that is cancelled due to failure by an Unapproved Vendor to supply Excipients or API in a timely manner or by OMEROS' failure to supply API in a timely manner if OMEROS is the party supplying the API pursuant to Section 4.2.1; provided, however, that at OMEROS' election (in OMEROS' sole discretion), DSM shall use commercially reasonable efforts promptly to reschedule any such cancelled production run. For clarity, if DSM is able to reschedule the cancelled production run, the full Product Price shall be charged for such rescheduled production run upon completion, notwithstanding OMEROS' prior payment of any applicable Cancelled Production Fee.

4.4.6 Quality Issues. In the event of any material quality issues arise with respect to an Unapproved Vendor, the Parties agree to consult in good faith to determine an appropriate course of action regarding such Unapproved Vendor and to mutually agree on a corrective action plan or a plan to secure an alternate Unapproved Vendor or Approved Vendor. Notwithstanding the foregoing, OMEROS shall be responsible for compensating DSM for all resources reasonably required to investigate and resolve such quality issues.

ARTICLE 5: REPRESENTATIONS, WARRANTIES AND COVENANTS; SPECIFICATIONS; QUALITY

5.1. Representations, Warranties and Covenants of DSM. DSM represents, warrants and covenants to OMEROS that: (a) it will assign personnel with appropriate experience and technical qualifications to perform the Manufacturing activities hereunder; (b) none of its officers, directors, employees, contractors or agents involved in the performance of this Agreement has been debarred or threatened with debarment pursuant to Section 306 of the FD&C Act or any similar law or convicted of a crime that could lead to such debarment, and it will not utilize the services of any individual or entity in the performance of the Manufacturing that has been debarred or threatened with debarment, convicted of a crime that could lead to debarment or subject to any other penalty or sanction by the FDA; (c) it will conduct the Manufacturing in compliance with Applicable Law including, without limitation, Applicable Pharmaceutical Law and Controlled Documents; (d) at the time of sale and shipment to OMEROS by DSM, the Product will conform to the Specifications as then in effect; (e) except to the extent attributable to the Specifications, OMEROS' written instructions, or to the extent existing in the API at the time of delivery to DSM, the Manufacture and supply of Product by DSM in accordance with the terms of this Agreement and the exploitation by OMEROS of such Product will not to DSM's knowledge infringe, misappropriate or otherwise violate the patent, trademark or other intellectual property rights of any Third Party, in each case as a result of the Manufacturing technology and know-how used by DSM; (f) the Commercial Product, at the time of delivery to OMEROS, will not be an article that may not be introduced into interstate commerce under the provisions of Sections 404 or 505 of the FD&C Act; (g) the Commercial Product, at the time of delivery to OMEROS, will not be adulterated, misbranded, misused, contaminated, tampered with or otherwise altered or mishandled by DSM within the meaning of the FD&C Act and Applicable Law; and

(h) the Commercial Product, at the time of delivery to OMEROS, will have a minimum shelf life equal to the established Commercial Product shelf life set forth in the applicable Product registration less three (3) months, except that in the case of an out of specification investigation, the Commercial Product, at the time of delivery to OMEROS, will have a minimum shelf life equal to the established Commercial Product shelf life set forth in the applicable Product registration less three (3) months less the duration of the out of specification investigation.

In the event that, during the Term of this Agreement, DSM receives notice of the debarment or threatened debarment of any individual or entity that has been utilized by DSM in connection with DSM's Manufacturing under this Agreement, DSM shall notify OMEROS in writing immediately, and OMEROS shall have the right to terminate this Agreement upon written notice without further cost or liability, except for payments of accrued and unpaid obligations to the date of termination.

DSM further represents, warrants and covenants that it has obtained (or will obtain prior to beginning Manufacturing), and will remain in compliance with during the Term, all permits, licenses and other authorizations which are required under Applicable Law for the Manufacturing and other services to be performed pursuant to this Agreement.

5.2. Representations, Warranties and Covenants of OMEROS. OMEROS represents, warrants and covenants to DSM that: (a) OMEROS will comply with Applicable Law in performing its obligations under this Agreement and that it will keep DSM fully informed of any development that would materially affect DSM's Manufacture of Products hereunder; (b) in the event OMEROS ships Product purchased from DSM outside of the United States, OMEROS will comply with all U.S. laws and regulations applicable to the export, resale or other disposition of such Product; (c) the Manufacture and supply of Product by DSM in accordance with the Specifications will not infringe, misappropriate or otherwise violate the patent, trademark or other intellectual property rights of any Third Party, excluding any infringement arising from the practice of DSM Intellectual Property; and (d) any Active Pharmaceutical Ingredients supplied by OMEROS to DSM hereunder will be suitable for the production of Product, will conform to the API Specifications at the time of delivery thereof, and will include an accurate API Certificate of Analysis.

5.3. Representations and Warranties by Each Party. Each Party hereby represents and warrants to the other Party that: (a) the person executing this Agreement is authorized to execute this Agreement on behalf of such Party; (b) this Agreement is legal and valid and the obligations binding upon such Party are enforceable by their terms, subject to the effects of bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity; (c) all requisite actions on the part of such Party and its officers and directors necessary for the authorization, execution and delivery of this Agreement and the performance of all obligations of such Party hereunder have been taken; and (d) the execution, delivery and performance of this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which such Party may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

5.4. No Further Warranties. To the maximum extent permitted by Applicable Law, the Parties neither make nor give any other express or implied (whether by statute, custom or otherwise) warranties in relation to each of their respective obligations, duties or activities owed or performed under this Agreement and hereby exclude any other such express or implied warranty in respect of that subject matter.

5.5. Limitation of Liability. Neither Party shall be liable to the other Party under this Agreement for incidental, indirect, special, consequential or punitive damages, including without limitation any claim for damages based upon lost profits or lost business opportunity. Other than in respect of (i) damages awarded in an underlying Third Party claim for illness, injury or death resulting from a defective Product, which are subject to the indemnity obligations of Article 14, (ii) fraud and fraudulent misrepresentation, or (iii) claims of willful misconduct or gross negligence, the aggregate damages for which either Party shall be liable to the other under this Agreement, including without limitation costs of rejected Batches, shall be limited on a Product specific basis to [†]. Finally and notwithstanding the foregoing, in no event shall DSM's liability for loss of API under this Agreement exceed [†].

5.6. Specification Changes.

5.6.1. OMEROS may amend the Specifications, the API Specifications or specifications for Excipients : (a) unilaterally and in its sole discretion for the purpose of complying with any Product Approval, Applicable Pharmaceutical Law or other Applicable Law, provided, however, that if DSM reasonably determines that it is incapable for technical reasons of compliance with such amended Specifications, API Specifications or specifications for Excipients, it shall promptly so notify OMEROS and OMEROS shall have the right at its discretion to terminate this Agreement as to the affected Product or (b) for any other reason upon commercially reasonable prior written notice (which shall not be interpreted to require in excess of [†] days' prior notice before implementation of the amendment) and subject to DSM's approval, such approval not to be unreasonably withheld. OMEROS shall promptly advise DSM in writing of such changes; and if such changes directly impact DSM's scheduling or costs, DSM shall promptly advise OMEROS as to any scheduling adjustments and/or cost increases for DSM caused by such changes. Prior to implementation of such changes, the Parties agree to negotiate in good faith in an attempt to reach agreement on (a) the new price for any Product which embodies such changes, reflecting any increases or decreases to DSM in the cost or quantities of materials consumed, provided that the change in price shall directly reflect any changes on DSM's costs in Manufacturing the Product (other than any such costs addressed in Section 5.6.2), and (b) any other amendments to this Agreement that may be necessitated by such changes (e.g., an adjustment to the lead time for Purchase Orders). DSM may not modify or amend the Specifications or the Manufacturing process, or change the site at which Manufacturing activities are performed hereunder, without the prior written consent of OMEROS.

5.6.2. OMEROS agrees to reimburse DSM for the reasonable expenses incurred by DSM as a result of the changes referenced in Section 5.6.1, including, but not limited to, reimbursing DSM for its validation and development costs, capital expenditure costs and costs for any packaging components or other materials rendered unusable as a result of such changes.

5.6.3. If during the Term OMEROS amends or is required by law to amend the Specifications, the API Specifications or specifications for Excipients so as to render the Active Pharmaceutical Ingredients, Excipients and/or packaging components for any Product obsolete, OMEROS shall reimburse DSM, at DSM's Acquisition Cost, for any such inventory, reasonably acquired by DSM in reliance upon this Agreement, rendered obsolete. DSM shall ship to OMEROS or OMEROS' designee or destroy, at OMEROS' sole election and expense, such obsolete inventory. In addition to reimbursement of DSM's Acquisition Cost and the costs of any shipment or destruction of such inventories, OMEROS shall pay DSM [†].

5.7. Quality Agreement. The Quality Agreement attached hereto as **ANNEX 3** (the "Quality Agreement") further details the quality assurance obligations and responsibilities of the Parties with respect to the Product. DSM and OMEROS agree that all quality related matters are addressed solely in the Quality Agreement and all matters other than quality related matters are addressed solely in this Agreement including Product Addendums hereto, and therefore no terms of this Agreement may be amended by any conflicting term that may be set forth in the Quality Agreement.

5.8. Duty of Cooperation. The Parties acknowledge that production of pharmaceutical products is inherently complex and requires close attention to all aspects of the Specifications, Excipients, Active Pharmaceutical Ingredients, production, storage, and shipment (collectively, "Process Requirements"). The Parties agree to notify each other promptly of any known problems with respect to the Process Requirements relating to Product and to work to resolve such problems in good faith and in a prompt and efficient manner so as to permit continued production and shipment of conforming Product, in accordance with all applicable regulatory requirements. Costs for correction of any such Process Requirements shall be allocated between the Parties in a fair and equitable manner and in accordance with the respective obligations of the Parties hereunder and under any related agreements.

5.9. Manufacturing Improvements.

5.9.1. Responsibilities. DSM shall use commercially reasonable efforts to identify and implement ways to reduce costs with respect to Manufacturing ("Manufacturing Improvements"), provided that Omeros has first had an opportunity to review and has provided advanced written consent to such Manufacturing Improvements, including capital expenditure, prior to implementation and such Manufacturing Improvements are made under appropriate change controls, including but not limited to improvements in quality and technology and the use of best practices relating to the Manufacture of Product and Applicable Pharmaceutical Law, reduction of waste associated with the Manufacture of Product, packaging and process time reduction in respect of the Manufacture of Product, and improvements in the supply chain efficiency between DSM and OMEROS in connection with the performance of this Agreement (including order/delivery process and delivery procedures).

5.9.2. Allocation of Benefits. Unless otherwise mutually agreed upon by the Parties, net benefits and any cost savings resulting from any improved efficiencies achieved as the result of Manufacturing Improvements shall be (i) allocated to DSM if such Manufacturing

Improvements were suggested by DSM, (ii) allocated to OMEROS if such Manufacturing Improvements were suggested by OMEROS or (iii) allocated equally to DSM and OMEROS if such Manufacturing Improvements were suggested jointly by DSM and OMEROS, except that in all cases DSM shall first recover any unreimbursed costs that it incurred to achieve the cost savings.

ARTICLE 6: FORECASTS; ORDERS; FAILURE TO SUPPLY

6.1. Long Term Forecast. Within [†] days after the Effective Date, OMEROS shall deliver to DSM a non-binding forecast of OMEROS' quantity requirements for each Commercial Product for the remainder of the Term, on a Contract Year-by-Contract Year basis (the "Long Term Forecast"). The Long Term Forecast shall thereafter be updated every [†] during the Term of this Agreement. If DSM is unable to accommodate any portion of the Long Term Forecast (other than the Firm Purchase Commitment), it shall notify OMEROS and the Parties shall agree on any revisions to the forecast and the Requirements Obligation.

6.2. Monthly Forecast. Beginning at least [†] days prior to the first month during which OMEROS requires Commercial Product from DSM hereunder, OMEROS shall submit to DSM a written non-binding estimate of its monthly requirements for such Product for each of the succeeding months in the Term (the "Monthly Forecast"). The Monthly Forecast shall be updated monthly on the [†] day of the month on a rolling basis. If OMEROS fails to update the Monthly Forecast, then DSM shall apply OMEROS' most recently forecasted requirements in planning the production schedule; and OMEROS shall be obligated to purchase such quantities to the extent that they become part of the Firm Purchase Commitment. If DSM lacks the capacity to Manufacture (i) quantities stated for any new month in the Monthly Forecast, or (ii) quantities in excess of previously forecasted quantities (collectively, the quantities in (i) and (ii) referred to as "Additional Quantities"), then DSM shall notify OMEROS in writing within five (5) calendar days after receipt of the Monthly Forecast; otherwise such Additional Quantities shall be deemed to have been approved and accepted by DSM. The Parties shall negotiate in good faith to resolve any issues in respect of the Additional Quantities that DSM is unable to accept for any month(s) stated in the Monthly Forecast, according to DSM's available capacity. Notwithstanding the two preceding sentences, OMEROS shall in any event be entitled to increase the aggregate quantity of Product specified during any given [†] period of the Monthly Forecast by [†] Batches of Commercial Product, except that DSM shall not be required to Manufacture such Additional Quantities that, at the time requested by OMEROS, are requested to be Manufactured within the current Firm Purchase Period if DSM does not at the time of such request have the capacity to Manufacture such excess quantities during the current Firm Purchase Period.

6.3. Firm Purchase Commitment. Commencing upon OMEROS' receipt of the first Product Approval for a Product and thereafter, the forecast for the current month plus the next [†] months following the current month of the Monthly Forecast (the "Firm Purchase Period") shall constitute a firm purchase and supply commitment (the "Firm Purchase Commitment"), which shall state in detail the quantities of Products ordered and the required delivery dates, and shall be binding on the Parties regarding Products to be purchased and supplied. The forecast for the remaining months of the Monthly Forecast

is for planning purposes only and shall not constitute a commitment to purchase or supply Product. In the event that OMEROS does not ultimately purchase the forecast quantities for each month of the Firm Purchase Commitment period, it shall be obligated to pay to DSM the applicable Cancelled Production Fee for any deficient quantities. However, if DSM is unable for any reason, other than the failure of OMEROS or OMEROS' Unapproved Vendor timely to provide API and/or Excipients as referenced in Section 4.2.4 or Section 4.4, to supply the Firm Purchase Commitment to OMEROS, OMEROS shall not be obligated to pay for that portion of the Firm Purchase Commitment which DSM could not deliver and DSM shall pay any penalties to the extent such penalties are owing under the provisions of Section 6.8.

6.4. Materials/Lead Times. DSM shall order Excipients and other materials necessary for the manufacture of Products in accordance with the lead-times set forth in **ANNEX 1** hereto. In addition, if due to unanticipated circumstances, any raw materials require a longer lead-time, DSM shall be entitled to order such materials as it reasonably deems appropriate to fulfill its obligations hereunder in a timely manner, provided that DSM shall consult with OMEROS before placing any such order.

6.5. Zero Quantities. If, at any time following the First Commercial Sale of a Product, OMEROS forecasts zero (0) quantities for [†] during the Term (the "Zero Forecast Period") for any reason, then DSM shall have the option, at its sole discretion, to provide a [†] notice to OMEROS of DSM's intention to terminate this Agreement with respect to such Product as of a specified date within the Zero Forecast Period; and OMEROS shall thereafter have [†] to (a) withdraw the zero forecasts and re-submit a non-zero quantity forecast, or (b) negotiate other terms and conditions on which this Agreement shall remain in force and effect with respect to such Product; otherwise, DSM shall have the right to terminate this Agreement at the end of the [†] notice period in accordance with Section 11.6.

6.6. Business Interruption/Allocation. If for any reason DSM experiences a business interruption or plant outage that prevents DSM from supplying full contract quantities of any Product to OMEROS for any period of time, then DSM shall give due notice of such conditions to OMEROS and OMEROS shall be accorded equal treatment as among all DSM customers and then-current production commitments on a pro rata basis, subject to the following priorities, provided that in all cases DSM shall use best efforts to ensure that OMEROS' Product does not stock out:

6.6.1. First (1st) priority: [†];

6.6.2. Second (2nd) priority: [†]; and

6.6.3. Third (3rd) priority: [†].

6.7. Obsolete Stock. OMEROS shall reimburse DSM for the Acquisition Cost of all materials that DSM has purchased pursuant to Section 6.4 for the manufacture of Products, where such materials were reasonably acquired, including without limitation with respect to cost, quantity and shelf life, and have expired or are rendered obsolete due to changes in artwork, specifications, or regulatory changes and can no longer be used in the manufacture of Products ("Obsolete Stock"). In addition to reimbursement of DSM's

Acquisition Cost for Obsolete Stock, OMEROS shall also pay DSM [†] for the handling of such Obsolete Stock, plus the costs of destruction thereof. DSM shall invoice OMEROS for the Acquisition Cost, administrative fee, and destruction costs within ninety (90) days of the date of destruction. OMEROS shall submit payment to DSM within thirty (30) days of the date of receipt of DSM's invoice.

6.8. Failure/Inability to Supply.

6.8.1. Late Delivery. If DSM fails to supply to OMEROS the quantities of Commercial Product specified in a Purchase Order by the Delivery Date specified therein, and such quantities are consistent with the then current Monthly Forecast, or are consistent with Additional Quantities accepted (or deemed accepted) pursuant to Section 6.2, then DSM shall apply a discount of [†] of the Product Price to the applicable invoice for the delayed shipment for each shipment which is delayed more than [†] beyond the Delivery Date or [†] of the Product Price to the applicable invoice for the delayed shipment for each shipment which is delayed more than [†] beyond the Delivery Date. DSM shall not delay any scheduled Manufacturing of a Batch for OMEROS for any reason based on the comparative economics of Manufacturing for a Third Party.

6.8.2. Failure to Supply at Least [†]. If DSM fails to, or is unable to, supply OMEROS with at least [†] of the aggregate quantity of Product set forth in all Purchase Orders submitted by OMEROS during [†] in which Purchase Orders are consistent with the then current Monthly Forecast and have been accepted by DSM, then any obligation of OMEROS under this Agreement to purchase quantities of such Product following the then-current Firm Commitment Period (pursuant to the Requirements Obligation or otherwise) shall be decreased by the percentage by which DSM's delivery of Product in such [†] period fell short of the quantity of Product ordered by OMEROS. Such decrease shall only apply to the Firm Purchase Commitment Period immediately following the period during which DSM failed to supply [†] of the Product.

6.8.3. Failure to Supply at Least [†]. If DSM fails to, or is unable to, supply OMEROS with at least [†] of the aggregate quantity of Product set forth in all Purchase Orders submitted by OMEROS during [†] in which Purchase Orders are consistent with the then current Monthly Forecast and have been accepted by DSM, then DSM's and OMEROS' senior executives shall promptly meet to develop a plan of corrective action for DSM and DSM shall use reasonable best efforts to supply OMEROS with additional Commercial Product up to the quantity previously requested in Purchase Orders unless requested otherwise by OMEROS or mutually agreed otherwise by the Parties. If a corrective action plan is not mutually agreed upon within twenty (20) days after the first meeting of such executives and then timely complied with, then OMEROS shall have the right, in its sole discretion, to terminate this Agreement.

6.9. Rework. DSM will not rework or reprocess Product unless authorized in advance by OMEROS in writing and then only at DSM's cost, unless otherwise authorized by OMEROS due to the rework being necessitated by the fault of OMEROS, and using a validated process for such rework or reprocessing of Product. Re-inspection does not constitute rework or reprocessing.

ARTICLE 7: PURCHASE OF PRODUCT; DELIVERIES

7.1. Purchase Orders.

7.1.1. Submission of Purchase Orders. Except to the extent the Parties may otherwise agree with respect to a particular shipment, all Commercial Products shall be ordered by OMEROS by submission to DSM of written purchase orders (each, a "Purchase Order"), stating the Commercial Product, Unit quantities, and Delivery Dates, which shall be sent to DSM not less than [†] prior to the Delivery Dates specified in such Purchase Orders. DSM shall accept or reject each Purchase Order in writing within [†] of receipt, and shall be deemed to have accepted a Purchase Order if not rejected within such [†] period. The quantity specified in a Purchase Order for a month shall be consistent with the then-current Monthly Forecast for such month, after taking into account OMEROS' ability to increase the aggregate quantity of Product specified in the Monthly Forecast as provided for in Section 6.2. Should OMEROS submit a Purchase Order to purchase Product in a given month in an amount greater than the quantity forecast for such month in the most recent Monthly Forecast provided by OMEROS to DSM pursuant to Section 6.2, then DSM shall use commercially reasonable efforts to supply such excess quantity but shall not be liable to OMEROS for any inability to do so. Upon receipt of each Purchase Order by DSM, DSM shall supply the Product(s) in such quantities and shall use its best efforts to deliver such Product(s) to OMEROS no later than [†] after the Delivery Dates specified in the Purchase Order. Development Product shall be ordered in accordance with the terms set forth in the applicable statement of work attached to **Annex 5**.

7.1.2. Changes in Purchase Orders. Once received by DSM, Purchase Orders may not be modified without DSM's prior written consent, which shall not be unreasonably withheld. Should OMEROS desire to increase the amount of Product to be supplied by DSM pursuant to any Purchase Order already submitted, OMEROS shall so notify DSM and DSM shall use commercially reasonable efforts to supply such excess quantity but shall not be liable to OMEROS for any inability to do so. OMEROS shall be charged a Cancelled Production Fee for any Purchase Orders cancelled by OMEROS (unless such cancellation occurs in conjunction with the termination of this Agreement by OMEROS pursuant to Section 11.3, 11.4, 11.5 or 17.1). Upon OMEROS' payment of the Cancelled Production Fee, the cancelled quantities shall be credited against the Requirements Obligation and be deducted from the Firm Purchase Commitment in proportion to the percentage of the Product Price for the cancelled quantity of Product paid.

7.1.3. Minimum Purchase Requirements Not Affected. If OMEROS requests any change to decrease the ordered quantity, any delays, or cancellation of any Purchase Order, and if DSM accepts such change, delay, or cancellation, DSM's acceptance shall not reduce or eliminate OMEROS' Firm Purchase Commitment and any other applicable minimum purchase requirements. Subject to Section 6.8.2, satisfaction of the Firm Purchase Commitment and other minimum purchase requirements shall be determined on the basis of actual quantities purchased (or Cancelled Production Fees paid) for the relevant period.

7.1.4. Additional Terms. Any additional or conflicting terms and conditions that may be printed on Purchase Orders issued by OMEROS or any acceptances issued by DSM shall have no force or effect between the Parties unless mutually agreed by the Parties in writing.

7.1.5. Purchase Quantities. All Commercial Product shall be ordered in Batch sizes, as set forth in **Annex 1** hereto or whole multiples thereof. Each Purchase Order shall specify the quantity of Units of Commercial Product being ordered. Quantities actually shipped pursuant to a given Purchase Order may vary from the quantities reflected in such Purchase Order by up to [†] above or below the stated quantities and still be deemed to be in compliance with such Purchase Order; provided, however, that OMEROS shall only be invoiced for actual delivered quantities.

7.2. Delivery Terms. The terms of delivery for the Product shall be F.O.B. DSM's [†] plant. Title and risk of loss and/or damage to the Product shall pass to OMEROS upon delivery of the Product to the carrier at DSM's [†] plant. All Products shall be (a) properly prepared for safe and lawful shipment (in compliance with Applicable Law) by DSM, (b) shipped to OMEROS' distribution center or other location designated by OMEROS, in accordance with OMEROS's approved packaging and shipping configurations, via the common carrier designated by OMEROS and (c) accompanied by appropriate transportation and other agreed upon documentation. No products of any Third Party shall be shipped with the Products. Shipping costs prepaid by DSM will be billed to OMEROS monthly by DSM on separate invoices. Each delivery of Product shall be accompanied by a Product Certificate of Analysis and other such documents as may be required by the Quality Agreement or Applicable Law.

7.3. Invoicing. DSM shall invoice OMEROS upon shipment of Commercial Product in accordance with Section 8.4. Validation Batches and pre-launch Commercial Product shall be invoiced in accordance with Section 2.3, irrespective of whether or not Product Approval has been granted by the FDA.

7.4. Import and Export Matters. As between the Parties, OMEROS shall prepare, obtain, and maintain all necessary import and export registrations relating to the Product and the API. DSM shall be responsible for Manufacturing all Product hereunder in accordance with Applicable Pharmaceutical Law.

ARTICLE 8: PRICE; PRICE INCREASES; ADDITIONAL PAYMENTS

8.1. Price. For Commercial Product, OMEROS shall pay DSM the Product Price set forth in **ANNEX 1** hereto, subject to adjustment as set forth in Section 8.2.

8.2. Price Adjustments.

8.2.1. API Supply. If OMEROS elects to require DSM to procure API, then the total Product Price payable for a Commercial Batch shall be adjusted by the Acquisition Cost of the API required to Manufacture such Commercial Batch plus [†].

8.2.2. Unapproved Vendor Price Changes. Any price increase in Excipients as implemented by Unapproved Vendors shall be passed through directly to OMEROS by a corresponding

increase in the Product Prices that directly reflects such increase, plus [†], unless such increases are directly billed by the Unapproved Vendor to OMEROS. As soon as DSM becomes aware of such price increases from an Unapproved Vendor, it shall provide notice to OMEROS, stating the effective date and the amount of the increase in the Product Price.

8.2.3. Costs of Specifications Changes. The Product Price may also be increased or decreased by mutual agreement of the Parties in connection with Specification changes made by OMEROS pursuant to Section 5.6. In the event that the Parties do not agree on the new Product Price that reasonably relates to the Specification changes to apply to Product embodying such Specification changes, DSM shall have the right in its sole discretion to terminate this Agreement.

8.2.4. Cost Reductions from Manufacturing Improvement Program. The Product Price shall be adjusted to reflect cost savings resulting from Manufacturing Improvements to the extent that the net benefits and cost savings resulting from such Manufacturing Improvements are allocated to OMEROS in accordance with Section 5.9.

8.2.5. Compliance with Foreign Regulatory Authorities. The Product Price may be increased by DSM, subject to OMEROS' approval, which shall not be unreasonably withheld, to reimburse DSM for any additional necessary services reasonably performed and costs reasonably incurred by DSM as necessary to comply with changes in regulatory requirements outside of the Territory.

8.3. Taxes. The Product Prices set forth in each Product Addendum included in **ANNEX 1** do not include sales, use, consumption, or excise taxes of any taxing authority. The amount of such taxes, if any, will be added to the Product Prices in effect at the time of shipment thereof and shall be reflected in the invoices submitted to OMEROS by DSM pursuant to this Agreement. OMEROS shall pay the amount of such taxes to DSM in accordance with the payment provisions of this Agreement.

8.4. Invoicing; Method of Payment. At the time of each shipment of Product hereunder, DSM shall invoice OMEROS, and OMEROS shall pay such invoices within thirty (30) days of the invoice date. Payments received after the due date may be subject to interest at a rate equal to the lesser of (a) [†] per month and (b) the maximum amount permitted by Applicable Law. All payments due hereunder to DSM shall be sent to DSM at the times set forth herein by check or wire transfer to such accounts as DSM may designate to OMEROS in writing from time to time in accordance with Section 21.11.

8.5. Audits. OMEROS shall have the option, on an annual calendar-year basis and more frequently for cause, to request an audit of any Product prices or other charges invoiced by DSM during the preceding Contract Year. Such audits shall be performed by an independent certified public accountant, mutually agreeable to OMEROS and DSM (the "Independent Auditor"), who shall be permitted to review DSM's records and accounts relating to this Agreement to verify that invoices issued hereunder were correctly prepared. The Independent Auditor shall only report to OMEROS whether the invoices were correctly calculated; and if not, the amount by which the invoices were over-stated or under-stated. OMEROS shall not otherwise have access to the financial records of DSM. The Independent Auditor shall be subject to the confidentiality provisions set forth

in Article 15. Promptly following the report of the Independent Auditor, the Party that overcharged the other Party or was undercharged by the other Party shall promptly make a reconciling payment to such other Party.

8.6. DSM shall maintain inventory control and reporting systems adequate to provide OMEROS upon request monthly, quarterly and annual reports of API and Excipient Supply inventory, work in progress inventory and Product inventory.

ARTICLE 9: RECALLS

9.1. Product recalls and FDA contacts relating to recall of Product shall be the responsibility of, and under the control of, OMEROS. However, in the event that either Party has reason to believe that any Products should be recalled or withdrawn from distribution, such Party shall promptly inform the other in writing prior to taking any such action. OMEROS shall notify the FDA and other Governmental Authorities, as appropriate, of any recall, and shall be responsible for coordinating all necessary activities regarding the action taken. DSM and OMEROS acknowledge that each Party has significant regulatory obligations; and accordingly, each Party shall fully cooperate with the other to complete the recall, and shall thereafter resolve any allocation of liability as may be appropriate in accordance with the terms of this Agreement.

9.2. OMEROS shall give DSM prompt written notice of any Product recalls that OMEROS believes were caused or may have been caused by DSM's failure to comply with this Agreement or the Specifications. If any Product is recalled as a result of the supply by DSM of Product that does not conform to the Specifications or other Product requirements of this Agreement, then subject to Sections 4.2.6 and 5.5, DSM shall promptly reimburse OMEROS for its reasonable expenses incurred as a result of such recall, and, at OMEROS' election, either refund OMEROS for any amounts paid and cancel any amounts payable pursuant to outstanding Purchase Orders under this Agreement relating to the recalled Product or replace the recalled Product with conforming Product at no cost to OMEROS. If OMEROS elects to utilize a Third Party to conduct a recall, OMEROS shall so notify DSM. Upon the occurrence of a Product recall event, OMEROS shall have the right to suspend Monthly Forecasts for the Product that is the subject of the recall and neither Party shall be subject to Firm Purchase Commitments related to the recalled Product until the cause of such recall has been identified and a corrective action plan mutually agreed upon by OMEROS and DSM has been implemented.

9.3. The Party responsible for causing a recall of Product shall bear the expenses of the recall. If each Party is partially responsible for causing the recall, the Parties will share the expenses of the recall in proportion to their respective responsibility.

9.4. OMEROS or its designated Third Party contractor shall maintain records of all sales of Commercial Product and customers sufficient to adequately administer a recall for the longer of (a) a period of [†], (b) a period of [†] and (c) such other period as required by Applicable Law. Subject to Sections 9.1, 9.2 and 9.3, OMEROS shall in all events be responsible for conducting any recalls of Product.

9.5. Over-Labeling. DSM shall not be responsible for reimbursing OMEROS for Product recalls that result directly from over-labeling or re-labeling of Product that is performed by OMEROS or any Third Party, after Product has been delivered by DSM to OMEROS. OMEROS shall indemnify and hold DSM harmless from any liability directly related to such over-labeling.

ARTICLE 10: VALIDATION; REGULATORY

10.1. Validation.

10.1.1. DSM shall prepare equipment qualification and manufacturing validation procedures, and shall perform qualification of equipment and utilities as well as validation of the manufacturing, packaging and cleaning processes in accordance with such procedures.

10.1.2. The Parties recognize that the Validation Batches are being manufactured in part to validate their manufacturability and conformity to the Specifications. Therefore, any part of the Validation Batches that the Parties determine does not meet the Specifications shall not be subject to the warranty contained in Section 5.1 or to the claims procedures set forth in Section 13; and, unless such nonconformity is due to the breach of this Agreement, negligence, willful misconduct or fault of DSM, OMEROS shall pay DSM the full Product Price for such non-conforming Validation Batches pursuant to Section 8.1. OMEROS shall not pay DSM for Validation Batches that do not meet the Specifications due to the breach of this Agreement, negligence, willful misconduct or fault of DSM.

10.2. Regulatory.

10.2.1. DSM shall provide OMEROS with standard regulatory support as identified under the heading “Regulatory Support” in **ANNEX 4** attached hereto. DSM shall also make available to OMEROS, at OMEROS’ request and expense, additional regulatory consulting services as mutually agreed upon. Regulatory support services, as identified in **ANNEX 4**, shall be at no additional charge to OMEROS; regulatory consulting services shall be billed at DSM’s standard hourly rates.

10.2.2. DSM shall provide OMEROS with all documents reasonably requested by OMEROS, and OMEROS shall provide DSM with all documents reasonably requested by DSM, relating to the FDA’s pre-approval inspection of DSM’s manufacturing facility. Omeros shall provide DSM with the relevant sections of the NDA. DSM shall provide OMEROS with a copy of the Annual Product Quality review and related data. OMEROS shall provide to DSM a copy of OMEROS’ annual report with respect to the manufacture and control of the Product. OMEROS shall be solely responsible for the CMC regulatory strategy.

10.3. Analytical and Validation Methodology. Any analytical and validation methodology supplied by OMEROS and required for use by DSM in the Manufacture of Product under this Agreement (a) shall be certified by OMEROS to the best of its knowledge to be appropriate for the intended use (e.g., cleaning verification, product release, in-process testing, and stability testing), (b) shall be validated per current regulatory guidelines, and (c) shall be readily available to DSM personnel during any regulatory inspection in the DSM site. Periodic re-certification of methods validations may be required in accordance

with Applicable Pharmaceutical Law. Required analytical and validation methodology that is not supplied by OMEROS (or not previously developed by DSM for OMEROS) shall be developed by DSM, at OMEROS' expense, according to DSM's standard rates for development.

10.4. Reference Standards. Reference standards required for API and key components of the Product that are readily available through the U.S. Pharmacopaeia shall be provided by DSM. If such reference standards (including any re-certifications thereof) are not readily available or must be made to order, OMEROS shall, at its sole discretion, either (a) obtain such reference standards at its sole expense or (b) require DSM to obtain them at OMEROS' expense.

10.5. Stability Studies. DSM shall provide stability studies once per year, per SKU or other approved matrix, at no additional cost to OMEROS. Additional stability studies shall be available to OMEROS at DSM's standard rates. Upon divestment of any Products hereunder, or upon termination of this Agreement, OMEROS shall arrange for transfer of any pending stability studies within ninety (90) days following divestment or termination, or, alternatively, OMEROS and DSM shall agree on any further costs, terms and conditions for DSM to complete the stability studies at the DSM facility.

10.6. Inspection and Audit Rights; Person-in-Plant.

10.6.1. During the Term and for the period required by Applicable Law, DSM shall maintain all records related to the Manufacturing process and DSM's Manufacturing of Product under this Agreement, including records regarding yield calculations, inventories, sampling records, and testing associated with Product. Retention samples shall be kept for a period of one (1) year after the expiration date for the applicable Batch or as otherwise set forth in the applicable Product Addendum. DSM shall track each Batch number of the Product, so as to be able to provide a full Manufacturing history upon OMEROS' request.

10.6.2. OMEROS shall be entitled, without charge, to [†] audit (an "OMEROS Audit") of DSM's facility annually with respect to DSM's Manufacturing activities hereunder.

10.6.3. Additional OMEROS Audits may be conducted:

10.6.3.1. other than in accordance with Sections 10.6.3.2, on no less than [†] days' notice subject to DSM's consent and at DSM's standard daily charge then in effect for such audits; and

10.6.3.2. as soon as reasonably practicable for DSM and without additional cost, in the event that DSM encounters a serious difficulty or failure in Manufacturing Product.

10.6.4. An OMEROS Audit shall last no longer than [†] days and may only be conducted during DSM's regular business hours. A maximum of three (3) named employees or consultants of OMEROS (the "Auditors"), all of whom must be subject to a confidentiality agreement with DSM, may attend the Audit. During the OMEROS Audit, the Auditors may enter those areas of DSM's facility relevant to Manufacturing, for the sole purpose of observing and inspecting the performance of the Manufacturing and those records of DSM specific

to or otherwise relevant to Manufacturing (including qualification systems, water systems and environmental monitoring).

10.6.5. DSM shall permit, upon reasonable notice and during reasonable times, representatives of competent Governmental Authorities and Regulatory Authorities to enter those areas of DSM's premises concerned with Manufacturing for the sole purpose of observing and inspecting the Manufacturing and those records of DSM specific to the Manufacturing.

10.6.6. During any inspection pursuant to Section 10.6.5, DSM shall provide reasonable assistance as requested by the relevant Governmental Authority or Regulatory Authority and shall promptly permit access to and (at OMEROS's reasonable expense) copy and verify relevant records and reports in DSM's possession, custody or control relating to the Manufacturing.

10.6.7. OMEROS shall be entitled to have up to two (2) of its employees temporarily located in DSM's facilities during the Manufacture of a Batch for the purpose of monitoring and observing operations or to participate in investigations into a failed Batch. Such employees shall be bound by the confidentiality obligations set forth in Article 15 with respect to DSM Confidential Information and any confidential information of Third Party obtained while at DSM's facilities and shall also comply with all relevant DSM policies and procedures of which DSM makes such employees aware including, but not limited to, DSM's security and alcohol and drug policies. OMEROS shall be solely responsible for any direct or indirect costs of such employees.

ARTICLE 11: TERM; TERMINATION

11.1. Term. Unless sooner terminated pursuant to the terms hereof or otherwise extended by mutual written agreement of the Parties, the term of this Agreement shall commence on the Effective Date and shall continue in force and effect until December 31, 2015 (the "Initial Term").

11.2. Termination by Mutual Agreement. This Agreement may be terminated at any time upon mutual written agreement between the Parties.

11.3. Termination for Default. This Agreement may be terminated by either Party in the event of the material breach or default by the other Party of this Agreement, provided that the non-breaching Party shall first give to the defaulting Party written notice of the proposed termination or cancellation of this Agreement, specifying the grounds therefor. Upon receipt of such notice, the breaching Party shall have thirty (30) days to respond by either curing such default; or by delivering to the other Party a certificate that such breach is not capable of being cured within such thirty (30) days and that the breaching Party requires additional time and is working diligently to cure such breach; provided, however, that in no event shall the time period for curing such a breach exceed ninety (90) days from receipt of the notice of breach. If the breaching Party does not so respond to the notice of breach or fails to work diligently and to cure such breach within the additional time set forth in this Section 11.3, then the non-breaching Party may terminate

this Agreement. Termination of this Agreement pursuant to this Section 11.3 shall not affect any other rights or remedies which may be available to the non-breaching Party.

11.4. Bankruptcy; Insolvency. Either Party may terminate this Agreement upon the occurrence of either of the following:

11.4.1. The entry of a decree or order for relief by a court having jurisdiction in respect of the other Party in an involuntary case under the Federal Bankruptcy Code, as now constituted or hereafter amended, or under any other applicable federal or state insolvency or other similar law and the continuance of any such decree or order is unstayed and in effect for a period of sixty (60) consecutive days; or

11.4.2. The filing by the other Party of a petition for relief under the Federal Bankruptcy Code, as now constituted or hereafter amended, or any other applicable federal or state insolvency or other similar law.

11.5. Termination by OMEROS. OMEROS may terminate this Agreement unilaterally and upon written notice to DSM pursuant to:

11.5.1. the second paragraph of Section 5.1;

11.5.2. Section 5.6.1;

11.5.3. Section 6.8.3; or

11.5.4. in the event that a Regulatory Authority withdraws Product Approval of the Product in the Territory.

11.6. Termination by DSM. DSM may terminate this Agreement unilaterally (i) pursuant to Section 6.5 or 8.2.3 upon written notice to OMEROS, or (ii) in the event that DSM is prohibited by mandate of a Regulatory Authority from continuing Manufacturing at the [†] facility due to regulatory requirements and the Parties cannot agree on the terms for the transfer of the Product to another DSM facility. For the avoidance of doubt, DSM will endeavor to supply Product to Omeros through the expiration of the Term and the termination right set forth in subsection (ii) above shall only apply if DSM is prohibited from continuing such manufacture through the length of the Term by the mandate of a Regulatory Authority. Moreover, in the event of termination pursuant to subsection (ii), the effective date of termination shall be the date that DSM is actually prohibited from manufacturing Product at the [†] facility.

11.7. Consequences of Expiration and Termination. Upon expiration or termination of this Agreement by either Party:

11.7.1. Except for cases of termination by OMEROS pursuant to Section 11.3 or 11.5, DSM shall Manufacture and deliver, and OMEROS shall purchase in accordance with the provisions hereof, any and all quantities of Product ordered by OMEROS in a Purchase Order prior to the date on which such notice is given. OMEROS, in its sole election, may cancel any quantities of Product already ordered in a Purchase Order, subject to payment of the applicable Cancelled Production Fee.

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

11.7.2. DSM shall return to OMEROS all unused quantities of Active Pharmaceutical Ingredient in DSM's possession that have been provided by OMEROS hereunder.

11.7.3. The Parties shall promptly agree on a procedure that allows OMEROS to take possession of any equipment located at DSM's facility that is owned by OMEROS (with OMEROS paying all reasonable, actual costs to access and remove such equipment, including DSM's reasonable and directly related facility restoration costs), or, at DSM's option and with OMEROS' consent, DSM may purchase such equipment from OMEROS by paying OMEROS the book value thereof as depreciated on a straight-line basis based on average years of usable life.

11.7.4. OMEROS shall purchase from DSM (a) at DSM's Acquisition Cost plus the lesser of [†], all Active Pharmaceutical Ingredients, Excipients and other materials acquired by DSM hereunder in reasonable reliance upon OMEROS' forecasts, (b) all work-in-progress for the Product at DSM's cost, and (c) all other Commercial Product then in DSM's possession; and (d) OMEROS shall compensate DSM for (i) all other non-cancellable commitments to Third Parties made by DSM to satisfy existing Purchase Orders, and (ii) all Obsolete Stock for which OMEROS has not reimbursed DSM in accordance with Section 6.7. Notwithstanding the foregoing, if any Cancelled Production Fee amount is less than an actual expense for such commitment (including restocking fees for returnable materials), OMEROS shall be required to reimburse DSM solely for the amount of the Cancelled Production Fee rather than for the applicable expense.

11.8. Survival. Upon expiration or termination of this Agreement, the obligations of the Parties under the following provisions shall survive in accordance with their terms: Article 1; Sections 4.1.5, 4.2.2, 4.2.6, 5.1 and 5.2 with respect to Product delivered pursuant to Section 11.7; 5.5, 7.2 and 8.4 with respect to Product delivered pursuant to Section 11.7; Article 9; Sections 10.6.1, 11.7 and 11.8; Section 12.1 (inclusive of Sections 12.1.1 and 12.2.2), Article 13 (except that, to the extent applicable, DSM shall be under no obligation to replace non-conforming Product with conforming Product under Section 13.1.4), Articles 14 and 15; Sections 16.1, 16.4 to 16.6; Articles 18, 19 and 20; Sections 21.1, 21.2, and 21.5 to 21.13.

ARTICLE 12: TECHNOLOGY TRANSFER

12.1. If OMEROS terminates this Agreement prior to the expiration of the Term, if DSM terminates this Agreement prior to expiration of the Term, or in connection with the end of the Term, and upon the written request of OMEROS, DSM agrees to use its commercially reasonable best efforts to provide OMEROS or its designee with all reasonably required assistance in order to transfer the then-current process for Manufacturing each applicable Product, at Omeros' sole discretion and at Omeros' sole expense, to not more than one manufacturer designated by OMEROS solely for the purpose of manufacturing such Product for OMEROS or its Affiliates or licensees (a "Technology Transfer"). All assistance provided by DSM shall be at DSM's standard consulting rates then in effect. Following DSM's receipt of such request, the Parties will establish, in good faith, a reasonable schedule and plan for completing such Technology Transfer and DSM will thereafter cooperate with OMEROS in implementing such plan,

but in no event shall any of the transition out of DSM's [†] facility occur beyond the expiration of this Agreement unless otherwise agreed to in writing. Such plan shall provide, without limitation, that DSM shall:

12.1.1. make available to OMEROS' designee, subject to any regulatory obligations and confidentiality obligations to Third Parties, copies of current versions of all Controlled Documents applicable to the Product, all Intellectual Work Product developed under this Agreement, but excluding all DSM Intellectual Property and DSM Intellectual Work Product, in each case to the extent relevant to the Manufacturing of Product and any other documentation then in the possession of DSM (excluding DSM Confidential Information) that is reasonably necessary to enable OMEROS' designee to Manufacture the applicable Product(s) in accordance with the Specifications; and

12.1.2. provide such other assistance as OMEROS may reasonably request to accomplish the Technology Transfer in an effective manner.

12.2. In addition to the Technology Transfer contemplated by Section 12.1, OMEROS may at any time request that the Manufacture of the Product be transferred to another manufacturing site owned by DSM. Any such transfer shall be subject to DSM having the capacity to manufacture at another manufacturing site owned by DSM and mutually agreed upon terms including, *inter alia*¸ (i) the terms and allocation of costs related to the transfer, (ii) revised terms related to the Manufacture of the Product at a different DSM manufacturing site including any appropriate amendments to this Agreement or a superseding agreement to this Agreement, and (iii) revised pricing for the Manufacture of the Product at a different DSM manufacturing site. Neither party will be obligated to provide such assistance if mutually agreed terms are not reached between the parties.

ARTICLE 13: CLAIMS

13.1. Claims.

13.1.1. In the event that any of the Product delivered to OMEROS' designated carrier by DSM fails to conform with the Product Specifications, OMEROS shall reject such Product by giving written notice to DSM within [†] after OMEROS' receipt of such Product and all associated quality assurance documents, including, without limitation, the Product Certificate of Analysis; provided, however, that if such a claim relates to a Latent Product Defect, then subject to and without limitation of Section 13.2, such claim shall be timely if made within [†] following the discovery of such Latent Product Defect.

13.1.2. For any claim relating to the container or container closure system for Products utilizing glass containers packaged by DSM, OMEROS shall make the subject vials available to DSM for analysis.

13.1.3. Claims relating to invoiced quantities or pricing shall be provided to the other Party within [†] following the date of the original invoice stating such quantities or prices, after which period such claims shall be deemed to have been waived; provided, however, that if such a claim relates to a Latent Product Defect, then subject to and without limitation

of Section 13.2, such claim shall be timely if made within [†] following the discovery of such Latent Product Defect.

13.1.4. Any notice given under this Article 13 shall specify the manner in which the Product fails to meet DSM's warranty or the Specifications. If it is determined by agreement of the Parties (or in the absence of agreement of the Parties, by a mutually acceptable independent laboratory or consultant whose fees shall be paid by the non-prevailing Party), that the non-conformity is due to damage to the Product caused by OMEROS or its agents or a Third Party other than DSM or a subcontractor or vendor under DSM's control, then DSM shall have no liability to OMEROS with respect thereto. Otherwise, DSM shall promptly, at OMEROS' election in its sole discretion, (a) credit OMEROS' account for, or refund to OMEROS, the price invoiced for such non-conforming Product as well as the Acquisition Costs (or, if applicable, pre-agreed designated costs) of the Active Pharmaceutical Ingredients and any other materials supplied by OMEROS to DSM under this Agreement that were used in the Manufacture of such non-conforming Product, together with all out-of-pocket expenses (including, without limitation, all shipping charges) associated with the purchase and return of the non-conforming Product, or (b) promptly replace the non-conforming Product with conforming Product at no cost to OMEROS.

13.2. Waiver of Claims. SUBJECT TO ARTICLE 14, CLAIMS ARISING HEREUNDER SHALL BE DEEMED TO HAVE BEEN WAIVED IF NOT BROUGHT WITHIN [†] FOLLOWING THE DATE OF THE OCCURRENCE GIVING RISE TO THE CLAIM, EXCEPT FOR CLAIMS RELATING TO LATENT PRODUCT DEFECTS WHICH CLAIMS SHALL BE DEEMED WAIVED IF NOT BROUGHT WITHIN [†] FOLLOWING DISCOVERY OF SUCH LATENT PRODUCT DEFECT, BUT IN NO CASE LATER THAN [†]. CLAIMS RELATING TO INVOICED QUANTITIES OR PRICING SHALL BE PROVIDED TO THE OTHER PARTY WITHIN [†] FOLLOWING THE DATE OF THE ORIGINAL INVOICE STATING SUCH QUANTITIES OR PRICES, AFTER WHICH PERIOD SUCH CLAIMS SHALL BE DEEMED TO HAVE BEEN WAIVED.

13.3. Disposition of Non-conforming Product. In any case where OMEROS expects to make a claim against DSM with respect to damaged or otherwise non-conforming Product, OMEROS shall not dispose of such Product without written authorization and instructions of DSM either to dispose of the Product or to return the Product to DSM.

13.4. Product Holds/Rejects. DSM shall promptly notify OMEROS of Product holds and/or rejects that may have an impact on Manufacturing and that may require OMEROS' approval prior to resolution.

ARTICLE 14: INDEMNIFICATION

14.1. Indemnification by OMEROS. OMEROS shall indemnify, defend and hold DSM, its Affiliates and their respective directors, officers, employees, agents, successors and assigns, harmless from and against any and all damages, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees) arising out of or in connection with:

14.1.1. OMEROS' breach of this Agreement;

14.1.2. any Third Party claim of illness, injury, or death caused by the use of any Product supplied by DSM hereunder that conformed to the Specifications and the other terms of this Agreement at the time of delivery to OMEROS, excluding such claims arising from a Latent Product Defect attributable to DSM's breach of this Agreement;

14.1.3. any claim by any employee of DSM, its subcontractors, or any Third Party of illness, injury or death arising out of OMEROS' breach of Section 2.4;

14.1.4. any proceeding instituted by or on behalf of a Third Party based upon a claim that the manufacture, use or sale of the Product infringes a United States patent or any other proprietary rights claimed by OMEROS and utilized with OMEROS' consent by DSM in the Manufacture of the Product; or

14.1.5. any act or omission of negligence, gross negligence, or willful misconduct by OMEROS or its respective directors, officers, employees, agents, or representatives in the performance of this Agreement.

14.2. Indemnification by DSM. DSM shall indemnify, defend and hold OMEROS, its Affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any and all damages, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees) arising out of or in connection with:

14.2.1. DSM's breach of this Agreement;

14.2.2. any Third Party claim of illness, injury or death caused by the use of any Product manufactured by DSM hereunder that did not conform to the Specifications or other terms of this Agreement at the time of delivery to OMEROS;

14.2.3. any proceeding instituted by or on behalf of a Third Party based upon a claim that the Manufacture of the Product infringes a United States patent or any other proprietary rights claimed by DSM (except for such claims as are subject to indemnity by OMEROS pursuant to Section 14.1.4); or

14.2.4. any act or omission of negligence, gross negligence, or willful misconduct by DSM or its respective directors, officers, employees, agents, or representatives in the performance of this Agreement.

14.3. Indemnification Procedures. A Party (the "Indemnitee") which intends to claim indemnification under this Article 14 shall promptly notify the other Party (the "Indemnitor") in writing of any action, claim or other matter in respect of which the Indemnitee or any of its Affiliates, or any of their respective directors, officers, employees or agents intend to claim such indemnification; provided, however, the failure to provide such notice within a reasonable period of time shall not relieve the Indemnitor of any of its obligations hereunder except to the extent the Indemnitor is prejudiced by such failure. The Indemnitee, its Affiliates, and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the

investigation, negotiation, compromise, settlement and defense of any action, claim or other matter covered by this indemnification. The Indemnitor shall be in charge of and control of any such investigation, negotiation, compromise, settlement and defense, and shall have the right to select counsel with respect thereto, provided that the Indemnitor shall promptly notify the Indemnitee of all material developments in the matter. In no event shall the Indemnitee compromise or settle any such matter without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; nor shall the non-consenting Party be bound by any such settlement. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense.

ARTICLE 15: CONFIDENTIALITY

15.1. During the Term and for a period of twenty (20) years following expiration or termination of this Agreement, each of OMEROS and DSM agrees not to publish, disclose or use for any purpose other than its performance under this Agreement, any information disclosed by the other Party and designated as proprietary or confidential ("Confidential Information"), including, without limitation, information printed on hard copy or stored on electronic media, audio or video tapes and disks, or information or knowledge visually acquired by or generated by OMEROS or DSM personnel in the form of written notes and memoranda memorializing information or knowledge acquired visually or aurally in the course of either Party's performance under this Agreement; provided, however, that for purposes of this Agreement, all OMEROS Intellectual Property and OMEROS Intellectual Work Product shall be deemed OMEROS' Confidential Information, and all DSM Intellectual Property and DSM Intellectual Work Product shall be deemed DSM's Confidential Information, regardless of which Party discloses such information to the other Party.

Each Party (the "Receiving Party") shall limit disclosure of Confidential Information received from the disclosing party (the "Disclosing Party") to only those officers and employees of the Receiving Party (or its Affiliates) who are directly concerned with the performance of this Agreement. Each Party shall advise such officers or employees upon disclosure of any Confidential Information to them of the confidential nature of the Confidential Information and the terms and conditions of this Article 15, and shall use all reasonable safeguards to prevent unauthorized disclosure of the Confidential Information by such officers and employees.

15.2. Both Parties agree that the following shall not be considered Confidential Information subject to this Agreement:

15.2.1. information that the Receiving Party can establish with written documentation is in the public domain by publication or otherwise, provided that such publication is not in violation of this Agreement or any other confidentiality agreement;

15.2.2. information that the Receiving Party can establish with written documentation was in the Receiving Party's possession prior to the time of disclosure by the Disclosing Party and was not acquired, directly or indirectly, from the Disclosing Party;

15.2.3. information the Receiving Party can establish with written documentation was lawfully received from a Third Party; provided, however, that such Third Party was not obligated to hold such information in confidence;

15.2.4. information that the Receiving Party can establish with written documentation was independently developed by the Receiving Party without access or reference to any Confidential Information; and

15.2.5. information that the Receiving Party is compelled to disclose by a court, administrative agency, Regulatory Authority or other tribunal; provided however, that in such case the Receiving Party shall immediately give as much advance notice as feasible to the Disclosing Party to enable the Disclosing Party to exercise its legal rights to prevent and/or limit such disclosure. In any event, the Receiving Party shall disclose only that portion of the Confidential Information that, in the opinion of the Receiving Party's legal counsel, is legally required to be disclosed and will exercise reasonable best efforts to ensure that any such information so disclosed will be accorded confidential treatment by said court, administrative agency, Regulatory Authority or tribunal.

15.3. Subject to Section 16.4, all Confidential Information shall remain the property of the Disclosing Party. Upon the expiration or termination of this Agreement, or at any time upon the written request of the other Party, the Receiving Party shall immediately return or destroy any Confidential Information of the Disclosing Party in the Receiving Party's possession, custody or control, except that the Receiving Party's legal counsel may keep one (1) copy for archival purposes. The Disclosing Party's failure to request the return of Confidential Information shall not relieve the Receiving Party of its confidentiality obligations under this Agreement.

15.4. Each Party acknowledges and expressly agrees that the remedy at law for any breach by it of the terms of this Article 15 shall be inadequate and that the full amount of damages that would result from such breach are not readily susceptible to being measured in monetary terms. Accordingly, in the event of a breach or threatened breach by either Party of this Article 15, the other Party shall be entitled to seek immediate injunctive relief prohibiting any such breach and requiring the immediate return of all Confidential Information. The remedies set forth in this Section 15.4, shall be in addition to any other remedies available for any such breach or threatened breach, including the recovery of damages from the breaching Party.

15.5. The terms and conditions of this Agreement, but not the fact of its existence, shall constitute Confidential Information, except that either Party may disclose such terms and conditions to its Affiliates in accordance with Section 15.1; provided, however, that notwithstanding the foregoing, the Parties acknowledge that each Party may be required to (and in such instance shall be permitted to) disclose the terms of this Agreement pursuant to its reporting obligations under the Securities Exchange Act of 1934, as amended (or other securities exchange requirements), and to file a copy of this Agreement as an exhibit to a periodic, quarterly or annual report required to be filed by such Party thereunder; provided, that the Party filing a copy of this Agreement as permitted by this Section 15.5 shall seek confidential treatment of the confidential terms of this Agreement, including but not limited to payment terms.

ARTICLE 16: INTELLECTUAL PROPERTY

16.1. Pre-Existing Intellectual Property. Any intellectual property rights and/or intellectual property owned by a Party or licensed by a Third Party to a Party as of the Effective Date, including, as the case may be, OMEROS Intellectual Property and DSM Intellectual Property (but only to the extent such OMEROS Intellectual Property or DSM Intellectual Property, as applicable, existed as of the Effective Date) ("Pre-Existing IPR") shall remain the sole and absolute property of the Party that owned or was licensed to use such Pre-Existing IPR. Nothing in this Agreement shall act as any assignment or transfer of the Pre-Existing IPR. The Pre-Existing IPR shall not be licensed to the other Party under this Agreement except as expressly provided for in Sections 16.2 and 16.3 .

16.2. License Grants to DSM. OMEROS hereby grants to DSM a royalty-free, worldwide, nonexclusive license (without the right to sublicense) to practice the OMEROS Intellectual Property and OMEROS Intellectual Work Product solely to the extent necessary or reasonably useful for DSM to perform its obligations hereunder. The foregoing nonexclusive license shall terminate upon the termination or expiration of this Agreement. Nothing in the foregoing license grant shall permit DSM to make any disclosure of OMEROS' Confidential Information or OMEROS Intellectual Property to a Third Party without the express prior written consent of OMEROS. This license does not prevent OMEROS from granting a license to or making use of the OMEROS Pre-Existing IPR, OMEROS Intellectual Property or OMEROS Intellectual Work Product for other purposes.

16.3. License Grants to OMEROS. DSM hereby grants to OMEROS (i) during the Term, a royalty-free, irrevocable, worldwide, nonexclusive, sublicensable license, but without the right to sublicense to any competing manufacturer without obtaining DSM's consent, to practice the DSM Intellectual Property and DSM Intellectual Work Product solely to the extent necessary or reasonably useful for Manufacturing Product and (ii) a royalty-free, worldwide, exclusive, sublicensable right of reference to the drug master file(s) for Product(s) prepared and maintained by DSM pursuant to this Agreement. This license does not prevent DSM from granting a license to or making any use of the DSM Intellectual Property or DSM Intellectual Work Product for any purpose.

16.4. Ownership of Intellectual Work Product.

16.4.1. OMEROS acknowledges that DSM shall be the sole and exclusive owner of all Intellectual Work Product [†] ("DSM Intellectual Work Product").

16.4.2. DSM acknowledges that OMEROS shall be the sole and exclusive owner of all Intellectual Work Product [†] ("OMEROS Intellectual Work Product"), and agrees promptly to disclose to OMEROS in writing any OMEROS Intellectual Work Product that DSM may develop solely or jointly during the Term. DSM hereby irrevocably assigns and transfers to OMEROS (and to the extent that an executory assignment is not enforceable, DSM hereby agrees to assign and transfer to OMEROS, in writing, from time to time, upon request) all of the right, title and interest that DSM has or may later acquire in and to the OMEROS Intellectual Work Product under copyright, patent, trade

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secret and trademark law, in perpetuity or for the longest period otherwise permitted by law. For purposes of clarity, all Intellectual Work Product that [†].

16.5. Right to File for Protection.

16.5.1. OMEROS shall have the sole right to prepare, file, prosecute and maintain patent applications and patents, continuations, continuations-in-part, divisions, reissues, additions, renewals, or extensions thereof, and all other applications considered desirable by OMEROS, disclosing or claiming the OMEROS Intellectual Work Product, in countries and regions of its choice throughout the world, for which OMEROS shall bear all costs. Either before or after the termination of this Agreement, DSM shall reasonably assist OMEROS in acquiring and maintaining such rights in, and confirming OMEROS' title to, the OMEROS Intellectual Work Product, at the request and sole expense of OMEROS. The assistance of DSM shall include but not be limited to executing assignments, declaration or other documents related to all patent, copyright, trademark and other applications considered desirable by OMEROS, cooperating in legal proceedings, and taking any other reasonable steps considered desirable by OMEROS.

16.5.2. DSM shall have the sole right to prepare, file, prosecute and maintain patent applications and patents, continuations, continuations-in-part, divisions, reissues, additions, renewals, or extensions thereof, and all other applications considered desirable by DSM, disclosing or claiming the DSM Intellectual Work Product, in countries and regions of its choice throughout the world, for which DSM shall bear all costs. Either before or after the termination of this Agreement, OMEROS shall assist DSM in acquiring and maintaining such rights in, and confirming DSM's title to, the DSM Intellectual Work Product, at the request and sole expense of DSM. The assistance of OMEROS shall include but not be limited to executing assignments, declaration or other documents related to all patent, copyright, trademark and other applications considered desirable by DSM, cooperating in legal proceedings, and taking any other steps considered desirable by DSM.

16.6. Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Article 16 by DSM are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code or analogous provisions of Applicable Law outside the United States, license of rights to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code or analogous provisions of foreign law. DSM hereby agrees that in the event of the commencement of a bankruptcy proceeding by or against DSM under the United States Bankruptcy Code or analogous provisions of Applicable Law outside the United States, OMEROS, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections thereunder. In addition, in the event of such proceedings, OMEROS shall be entitled to a complete duplicate or (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property which, if not already in OMEROS' possession, shall be promptly delivered to it upon any such commencement of a bankruptcy proceeding upon OMEROS' written request therefor.

ARTICLE 17: FORCE MAJEURE

17.1. Effects of Force Majeure. Neither Party shall be held liable or responsible for failure or delay in fulfilling or performing any of its obligations under this Agreement if such failure or delay is due to any condition beyond the reasonable control of the affected Party including, without limitation, Acts of God, strikes or other labor disputes, war, riot, earthquake, tornado, hurricane, fire, civil disorder, explosion, accident, flood, sabotage, lack of or inability to obtain adequate fuel, power, materials, labor, containers, transportation, supplies or equipment, breakage or failure of machinery or apparatus, national defense requirements, or supplier strike, lockout or injunction (a "Force Majeure Event"). In the event that DSM is unable to meet Purchase Order Delivery Dates because of any Force Majeure Event for more than [†], OMEROS may (a) terminate this Agreement without penalty on [†] notice to DSM and (b) cancel any and all outstanding Purchase Orders. In addition, during the continuation of any Force Majeure Event, OMEROS shall be free to source its requirements for Product from Third Parties with respect to any Purchase Order as to which DSM is unable to meet the specified Delivery Dates because of the Force Majeure Event. Any Firm Purchase Commitment and all other minimum purchase requirements shall be reduced, without penalty, by the quantity of Product covered by any Purchase Orders cancelled pursuant to this Section 17.1. Upon cessation of such Force Majeure Event, the Parties shall promptly resume performance on all Purchase Orders which have not been terminated .

17.2. Notice of Force Majeure Event. In the event either Party is delayed or rendered unable to perform due to a Force Majeure Event, the affected Party shall give notice thereof and its expected duration to the other Party promptly after the occurrence of the Force Majeure Event; and thereafter, the obligations of the affected Party will be suspended during the continuance of the Force Majeure Event. The affected Party shall take commercially reasonable steps to remedy the Force Majeure Event with all reasonable dispatch, but such obligation shall not require the settlement of strikes or labor controversies on terms unfavorable to the affected Party.

ARTICLE 18: LEGAL COMPLIANCE

18.1. Legal Compliance. Each Party shall comply in all material respects with all Applicable Law in the performance of its obligations pursuant to this Agreement.

ARTICLE 19: PRESS RELEASES; USE OF NAMES

19.1. Press Releases. Any press release, publicity or other form of public written disclosure related to this Agreement prepared by one Party shall be submitted to the other Party prior to release for approval, which approval shall not be unreasonably withheld or delayed by such other Party; provided, however, that OMEROS and DSM's parent company may announce the signing of this Agreement and the names of the Parties hereto (but none of the terms herein) in their quarterly results release without such prior approval .

19.2. Joint Press Release. Following the Effective Date, the Parties will agree to issue a joint press release, the form and content of which shall be mutually agreed by the Parties with respect to the transactions contemplated by this Agreement and which shall note

the strengths of each Party hereto and the benefits each will receive pursuant to the terms of this Agreement and shall include a quotation from the Chief Executive Officer or division President of each Party.

19.3. Use of Names. Except as expressly provided or contemplated hereunder and except as otherwise required by Applicable Law, no right is granted pursuant to this Agreement to either Party to use in any manner the trademarks or name of the other Party, or any other trade name, service mark, or trademark owned by or licensed to the other Party if connection with the performance of this Agreement. Notwithstanding the above, as required by Applicable Law, OMEROS, DSM and their respective Affiliates shall be permitted to use the other Party's name and to disclose the existence and terms of this Agreement in connection with securities or other public filings subject to the protections of confidential information as set forth in Section 15.5.

ARTICLE 20: DISPUTE RESOLUTION; VENUE

20.1. Arbitration. The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the term of this Agreement that relates to either Party's rights and/or obligations hereunder. In the event of the occurrence of such a dispute, either Party may, by notice to the other Party, have such dispute referred to their senior officers as shall be designated by each Party for attempted resolution through good faith negotiations within thirty (30) days after such notice is received. In the event the designated officers are not able to resolve such dispute within such thirty (30) day period, or such other period of time as the Parties may mutually agree in writing, the Parties shall be obligated to submit the dispute to binding arbitration in accordance with the rules of the American Arbitration Association ("AAA") for commercial arbitration, utilizing three (3) arbitrators mutually agreeable to the Parties. If the Parties are unable to reach agreement as to one or more of the arbitrators, the arbitrators shall be chosen in accordance with the AAA commercial arbitration rules. The arbitrators shall present a detailed written statement of their findings; and the Parties shall be bound thereby. The arbitration proceedings and any documents or other information disclosed in connection therewith shall be subject to the requirements of confidentiality as set forth in Article 15.

20.2. Venue. The arbitration shall take place in a mutually agreeable location, but if the Parties cannot agree as to the location, the arbitration shall take place in New York, New York. The arbitrators shall apply the law of the State of New York without regard to conflicts of law provisions.

ARTICLE 21: MISCELLANEOUS

21.1. Insurance. During the Term and for at least three (3) years thereafter, each Party shall at all times maintain all necessary insurance coverage with sound and reputable independent insurers at commercially reasonable levels of coverage or shall be self insured having regard to the nature, type, scope and size of the business it conducts and all its respective activities and obligations under this Agreement. Each Party shall maintain general liability insurance with minimum coverage equal to [†]. Each Party shall, upon reasonable request of the other Party, produce satisfactory evidence that all

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insurance premiums have been paid and kept up to date and are kept in accordance with local insurance laws or regulations from time to time in force, or shall furnish appropriate certificates of insurance showing proof of coverage. The insurance coverage may be provided through a combination of primary, excess/umbrella or self-insured retention, and shall not serve to operate as a limitation on the recovery of any claim. Each Party shall include the other Party as an additional insured on its policies of insurance, as the other Party's interests may be affected pursuant to this Agreement.

21.2. Independent Contractors. The relationship between OMEROS and DSM is that of independent contractors and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, or of principal and agent between OMEROS and DSM. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

21.3. Assistance from OMEROS. To assist DSM in its performance of this Agreement, OMEROS shall provide DSM, in a timely fashion, with all relevant information, documentation and data (including without limitation any information, documentation and data relating to product safety and information, documentation and data, including without limitation NDA and/or other OMEROS Regulatory Documentation numbers and NDC codes, reasonably necessary for DSM to drug list a Product) that is necessary or appropriate for DSM's performance hereunder. If requested by DSM to provide such information, OMEROS shall provide such information (or an explanation of the legitimate reason for any delay and a projected date by which such support or information will be provided) within ten (10) business days of DSM's request. In the event OMEROS is to review or approve any information, documentation, data or samples prepared or supplied by or on behalf of DSM, it shall complete such review and approval process within in a timely fashion.

21.4. Assignment; Subcontractors. Without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned, or delayed, neither Party shall sell, transfer, assign, delegate, pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that either Party may make such an assignment without the other Party's consent to its Affiliate or to a successor, whether in a merger, sale of stock, or sale of assets to which this Agreement pertains and provided, further, that OMEROS may make such an assignment without DSM's consent to a Third Party to which OMEROS grants commercialization rights to Product in the Territory. With respect to an assignment to an Affiliate, the assigning Party shall remain responsible for the performance by such Affiliate of the rights and obligations hereunder. Any attempted assignment or delegation in violation of this Section 21.4 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of DSM or OMEROS as the case may be. In the event either Party seeks and obtains the other Party's consent to assign or delegate its rights or obligations to another Party, the assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement. DSM may, only with OMEROS' prior written consent at Omeros' reasonable discretion, utilize subcontractors to perform any part of this Agreement.

21.5. Continuing Obligations. Termination, assignment or expiration of this Agreement shall not relieve either Party from full performance of any obligations incurred prior thereto.

21.6. Waiver. Neither Party's waiver of any breach or failure to enforce any of the terms and conditions of this Agreement, at any time, shall in any way affect, limit or waive such Party's right thereafter to enforce and compel strict compliance with every term and condition of this Agreement.

21.7. Severability. Each Party hereby expressly agrees that it has no intention to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries; that if any word, sentence, paragraph, clause or combination thereof in this Agreement is found by a court or executive body with judicial powers having jurisdiction over this Agreement or either Party, in a final unappealed order, to be in violation of any such provisions in any country or community or association of countries, such words, sentences, paragraphs, clauses or combination shall be inoperative in such country or community or association of countries and the remainder of this Agreement shall remain binding upon the Parties, so long as enforcement of the remainder does not violate the Parties' overall intentions in this transaction.

21.8. Headings. The headings in this Agreement are for convenience of reference only and shall not affect its interpretation.

21.9. Construction. This Agreement has been jointly prepared on the basis of the mutual understanding of the Parties and shall not be construed against either Party by reason of such Party's being the drafter of any portion of this Agreement.

21.10. Annexes, Schedules and Attachments. Any and all annexes, schedules and attachments referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.

21.11. Notices. All notices and other communications required or permitted to be given under this Agreement shall be in writing and shall be delivered personally or sent by (a) registered or certified mail, return receipt requested, or (b) a nationally-recognized courier service guaranteeing next-day delivery, charges, and shall be deemed to have been given upon mailing. Any such notices shall be addressed to the receiving Party at such Party's address set forth below, or at such other address as may from time to time be furnished by similar notice by either Party:

If to DSM: DSM Pharmaceuticals, Inc.
5900 Martin Luther King Hwy.
Greenville, NC 27834
Attn: President & Business Unit Director

If to OMEROS: Omeros Corporation
1420 Fifth Avenue, Suite 2600
Seattle, WA 98101

Attn: Chief Executive Officer

With a copy to:
Omeros Corporation
201 Elliott Avenue West
Seattle, WA 98119
Attn: General Counsel
e-mail: mkelbon@omeros.com

21.12. Counterparts. This Agreement and any amendment or supplement hereto may be executed in any number of counterparts and any Party hereto may execute any such counterpart, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument. The execution of this Agreement and any such amendment or supplement by any Party hereto will not become effective until counterparts hereof have been executed by both Parties hereto.

21.13. Governing Law; Entire Agreement. The validity, interpretation and performance of this Agreement shall be governed and construed in accordance with the laws of the State of New York without regard to the conflicts of laws provisions thereof. This Agreement constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement. No terms, conditions, understanding, or agreement purporting to modify or vary the terms of this Agreement shall be binding unless hereafter made in writing and signed by the Party to be bound. No modification to this Agreement shall be effected by the acknowledgment or acceptance of any Purchase Order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein.

[Signatures on following page]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the day and year first above written.

DSM Pharmaceuticals Inc. ("DSM")

By: /s/ Laura Parks
Laura Parks, President & Business Unit Director

Omeros Corporation ("OMEROS")

By: /s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D., Chairman & CEO

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

ANNEX 1:

**PRODUCT SPECIFICATIONS, PRICING,
AND OTHER INFORMATION FOR OMS302**

1. Product Specifications:

   [†]

2. Active Pharmaceutical Ingredients and API Specifications:

   [†]

   [†]

3. Supplier of API:

   [†]
   [†]

4. Excipients:

   [†]

   [†]

5. Packaging Specifications:

   [†]
   [†]
   [†]

Product Pricing: Omeros recognizes that pricing will need to be adjusted if there are any changes in the assumptions below.

Presentation	Batch Size	Total Batch Price	Total Price per Vial
[†]	~[†]	$ [†]	$[†]
[†]	~[†]	$[†]	$[†]

1. Pricing assumes [†].
2. Pricing assumes [†].
3. Pricing assumes [†].
4. Pricing assumes [†].
5. Pricing assumes [†].
6. Pricing assumes [†].
7. Pricing assumes [†].
8. Pricing assumes [†].
9. [†].
10. [†].

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6. Special Equipment: [†].

7. Lead Times for Purchase Orders and Inventories:

Packaging
[†]
[†]
[†]

Materials
[†]
[†]
[†]
[†]

8. Special requirements for procurement of API and/or Excipients: None.

9. Any Agreed Additional Compliance Regions: None.

10. Commercial Product Batch size: ~[†] per Batch

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ANNEX 2: CAPITAL / EQUIPMENT

[†]

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ANNEX 3: QUALITY AGREEMENT

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

QUALITY AGREEMENT

By and Between

Omeros Corporation
201 Elliott Avenue West
Seattle, WA 98119
(Hereinafter called "Omeros")

And

DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, North Carolina 27834
(Hereinafter called "DSM")

/s/ Catherine A. Melfi

Date: August 27, 2013

Catherine A. Melfi, Ph.D.
Vice President,
Regulatory Affairs and Quality Systems

/s/ Warren Horton

Date: August 23, 2013

Warren Horton
Vice President,
Quality Operations & Regulatory Affairs

This quality agreement is effective when signatures of all parties are complete.

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This Quality Agreement defines the roles and responsibilities of OMEROS and DSM in order to maintain cGMP compliance when providing services and/or Products for OMEROS. This Quality Agreement shall be incorporated within and constitute a part of the Pharmaceutical Manufacturing and Supply Agreement by and between OMEROS and DSM (the "Supply Agreement"). Given that all quality related matters are addressed solely in this Quality Agreement and all matters other than quality related matters are addressed solely in the Supply Agreement, no terms of this Quality Agreement shall act to amend any term of the Supply Agreement.

This Quality Agreement takes the form of a detailed checklist of the activities associated with pharmaceutical production and related support activities. Responsibility for each activity is assigned to either OMEROS and/or DSM in the appropriate box in the Delegation Checklist. For each responsibility listed, the respective party is required to put into effect all applicable procedures and to take all necessary actions to effectuate that responsibility in accordance with cGMP's, applicable laws, and the marketing authorizations.

No changes to the terms of this Agreement may be made unless by written amendment, mutually agreeable to both parties, attached hereto and made a part hereof. The parties will review the Quality Agreement once every three years unless required sooner to incorporate changes in services and/or Product(s) and issue a revised document or appendix, as appropriate. The Product(s) referred to herein as Product and the Product development stage (i.e. development, clinical trial material, commercial) are defined in Appendix I. To facilitate routine communications between the parties, company contact individuals are provided in Appendix II. OMEROS and DSM contact individuals may be updated as required by notification to either party.

This Quality Agreement shall expire upon the expiration or termination of the Supply Agreement, except those obligations, which, by their nature, shall survive the expiration or termination of this Quality Agreement, such as ongoing regulatory requirements set forth in this Quality Agreement, and including, for example, maintaining records and supporting product complaint investigations.

RESPONSIBILITY DELEGATION CHECKLIST

	Responsibilities	OMEROS	DSM
1 GMP STANDARDS			
1.1	Services contracted will comply with applicable domestic and international current good manufacturing practices (cGMP) as referenced in the Supply Agreement (such as USP Pharmacopoeia, European Pharmacopoeia, and other relevant international, federal, state, and local laws and regulations in effect in the US and the European Union.) appropriate to the product development stage and distribution.		√
1.2	Will provide prior notification when changing the country of market and to ensure existing product operations comply with the specific market and applicable regulations.	√	
1.3	Agrees to comply with policies and procedures adopted by DSM to establish and maintain cGMP, including investigative methodology that governs how DSM interprets and releases data in support of final batch disposition.	√	
2 QUALITY PRESENCE			
2.1.	Shall work collaboratively to conduct periodic meetings to discuss Product quality-related data, future planning, regulatory updates, and such other matters as may be requested by a Party and agreed by the other Party.	√	√

Responsibilities		OMEROS	DSM
2.2	Will permit OMEROS to perform a minimum of [†] standard cGMP annual compliance audit for the services contracted, upon reasonable notification from OMEROS, with actual audit dates subject to mutual agreement. Such audits shall not exceed [†] days and shall have no more than four (4) auditors. OMEROS representatives will be escorted by DSM personnel at all times and will only have access to the facility and records relating to the services and Products under contract with OMEROS. An extension of the audit frequency may occur at any time with written agreement from both Parties.		√
2.3	Notwithstanding the foregoing, will permit OMEROS to conduct an additional audit on a date mutually agreed upon by both parties to the extent necessary to address significant events (i.e. critical regulatory action pertinent to product production area or existence of multiple quality system events within DSM control). Such audits shall be scheduled promptly after Senior Management agreement of the event audit and agenda scope.		√
2.4	Will report audit findings verbally at the close of the audit and will provide a written report within [†] days of the audit.	√	
2.5	Response will include root cause evaluation, corrective actions, preventive actions, and remedial actions, where appropriate, and shall include a timeline for completion of each action. The response will be sent to OMEROS within [†] days from report receipt or in a mutually agreed upon time period.		√
2.6	Responses that OMEROS deems are not acceptable, incomplete, or inadequate will be reviewed with the respective Quality Management from both Parties for resolution. If Parties are unable to resolve, the matter shall be escalated to site management before proceeding with dispute resolution provisions.	√	√
2.7	Will permit OMEROS personnel to observe the manufacture of Product at any time upon reasonable notification from OMEROS and for a reasonable duration. The number of personnel and duration of visit will be agreed upon prior to the visit.		√
3 REGULATORY AGENCY INSPECTIONS			
3.1	Will notify OMEROS within [†] days of any regulatory agency action that specifically affects the contracted services and/or Products to be supplied pursuant to the Supply Agreement.		√
3.2	Notify OMEROS of any regulatory agency inspection specifically impacting the products covered by this Agreement on the [†] of initiation/notification of the audit by the regulatory agency.		√
3.3	Reserves the right to be available on site during an agency inspection when the inspection pertains to Product.	√	
3.4	Will respond to the regulatory agency in a timely manner after consultation with OMEROS on any OMEROS product-specific citation. DSM will forward appropriately redacted regulatory agency documentation (e.g., EIR) and responses that pertain to OMEROS Product within [†] days of receipt or completion of submission.		√
3.5	Notify DSM of any regulatory agency inspection specifically impacting the products covered at OMEROS or affiliate by this Agreement on the [†] day of the audit.	√	
3.6	Reserves the right to present site data and/or procedures upon specific requests regarding DSM responsibilities.		√
3.7	Data specific to Product produced at DSM and that is maintained by OMEROS (e.g. Product Quality Review Data assembled by OMEROS, Stability not performed by DSM, etc.) will be made readily available to DSM during regulatory inspections in order for DSM to fulfill regulatory requests or address regulatory audit actions.	√	
4 PREMISES			
4.1	Will perform pharmaceutical production and related support activities at the facility.		√
4.2	Will maintain premises and equipment used to manufacture the Products according to current regulatory requirements.		√

Responsibilities		OMEROS	DSM
4.3	Manufacture the Products in a suitably controlled environment; and such facilities will be regularly monitored for parameters critical to the process in order to demonstrate and maintain compliance with (i) applicable GMP guidelines and (ii) mutually agreed specifications.		√
4.4	Will maintain controlled access to the premises. All visitors shall comply with applicable access policies, dress code, cell phone usage, camera, security, and safety requirements.		√
4.5	Restrict the following product types (classification) from being introduced as noted into the existing common site manufacturing operations. • Insecticides/Pesticides • Live Organisms (Live or attenuated virus) • Beta Lactams, Penicillin, and Penicillin derivatives • Non-Treated Blood Product • Hormones • Cytotoxic* *Segregated site manufacturing option available for product classification		√
4.6	[†] Will notify OMEROS of [†] • [†] • [†] • [†] [†]. The prior notification shall provide sufficient information to perform an assessment to identify any issue for the Product and agency requirements.		√
4.7	Will notify DSM of any commitments and/or restrictions associated with the manufacturing of the Products in a multiple-product manufacturing facility. In the event that OMEROS identifies a potential regulatory requirement related to a new product introduction that would affect Product activity, the parties will identify actions to resolve the requirement.	√	
4.8	Will notify agencies, as appropriate, of intent to produce, package, label, warehouse, quality control test, release or ship any new product at the facility classified within the prohibited or highly active compounds in accordance with the regulations and other requirements of the agencies.		√
5 TRAINING / QUALIFICATION			
5.1	Shall maintain a program to assure that all personnel engaged in the operations related to the PRODUCTS have the education, training, and experience to properly perform their assigned functions in compliance with cGMP.		√
5.2	Training shall be in the particular operations that the employee performs and in current applicable manufacturing regulations, as they relate to the employee's functions.		√
5.3	Training records for all personnel shall be maintained and made available upon request or pursuant to any regulatory review.		√
6 DOCUMENTATION AND CHANGE MANAGEMENT			
6.1	Will notify OMEROS prior to implementation of any proposed changes to facilities, equipment, or the manufacture that may impact the quality, purity, safety, effectiveness or regulatory status of Product.		√
6.2	All changes to the Product related documents (i.e. master batch record, analytical method) shall proceed through a technical and cGMP impact assessment according to DSM's change control program. OMEROS will participate in review and approval of the changes.	√	√

Responsibilities		OMEROS	DSM
6.3	The documents which (a) contain changes that may affect OMEROS' regulatory submissions or the support system and which (b) have a direct impact on the quality systems affecting OMEROS' Product will be reviewed and assessed by OMEROS' designated personnel for regulatory advice and implementation requirements and such approval shall not be unreasonably withheld or delayed. If the change has the potential to require a regulatory submission, DSM will support regulatory submission related scope of work request(s), if necessary.	√	√
6.4	Shall not make any changes to DSM-owned or DSM-controlled cGMP documentation without the consent of DSM in order to ensure that all cGMP documentation, which is maintained at DSM and subject to regulatory review, is consistent with information filed with regulatory authorities.	√	
7 RAW MATERIALS/ PACKAGING COMPONENTS			
7.1	Shall provide specifications to DSM for raw materials/primary packaging components to be supplied by DSM.	√	
7.2	Shall implement and maintain specifications in DSM system for all Product specific materials and components.		√
7.3	Shall be responsible for using materials/primary packaging components from approved vendors agreed upon by both parties. Will maintain a Vendor Qualification program for DSM approved vendors.		√
7.4	For vendors designated or utilized by OMEROS which are not DSM-approved vendors, shall be responsible for qualifying and overseeing such vendors and will provide a Certificate of Compliance statement for such vendors upon request.	√	
7.5	Shall be responsible for ensuring that all raw materials / primary packaging components and related testing information supplied by OMEROS or by its designated vendors for use in manufacture of the Products are in full compliance with the specifications registered.	√	
7.6	Shall be responsible for ensuring that all raw materials / packaging components from DSM designated vendors for use in manufacture of the Products are in compliance with the specifications provided by OMEROS.		√
7.7	Shall provide a Certificate of Analysis for materials supplied directly by OMEROS.	√	
7.8	Will provide details of any storage and shipping conditions for the API supplied by OMEROS.	√	
7.9	OMEROS shall review and approve all Product specific raw materials and primary packaging components specifications.	√	
7.10	Prior to use, all raw material / packaging components must be found to be acceptable against pre-established specifications and in compliance with applicable TSE/BSE requirement.		√
7.11	Will utilize where practicable, components in a "First Expired, First Out" basis (i.e. the oldest materials will be consumed first in production operations).		√
8 PRODUCTION			
8.1	Will manufacture, test, package, and label Products according to documents approved by DSM and OMEROS.		√
8.2	Will document any atypical nonconforming events and deviations from approved procedures and/or master batch record and notify OMEROS. Any nonconforming event/deviation occurrence identified will follow the DSM notification and investigation process and procedures as defined in Section 15.		√
8.3	Will perform environmental monitoring in accordance with DSM procedures.		√
8.4	Will not rework or reprocess Product unless authorized in advance by OMEROS in writing and there is a validated process for such rework or reprocessing of Product. Will document reasoning and justification for any reworking and reprocessing. Re-inspection does not constitute rework or reprocess.	√	√

	Responsibilities	OMEROS	DSM
9 LABORATORY ANALYSIS			
9.1	OMEROS shall be responsible for providing approved copies of the current and complete regulatory filed analytical methods and supporting validation documentation relating to the Products for application by DSM in the production process, including API and raw materials, in-process product testing, product batch release, and cleaning validation.	√	
9.2	Complete a method transfer of any test method developed by OMEROS prior to DSM releasing Products for shipment utilizing the transferred method(s).	√	√
9.3	Will perform method validations/qualifications required by OMEROS. Will verify compendia test methods (e.g., USP, EP, JP).		√
9.4	Supply any required reference standards that are not readily available through a commonly recognized source. Such reference standards must be accompanied by a Certificate of Analysis listing the expiration date and any correction factors that need to be applied.	√	
9.5	Will establish analytical methods after review and approval by OMEROS and maintain those analytical methods.	√	√
9.6	May perform confirmatory testing during the initial term of this Agreement to validate the DSM data. Periodically thereafter, may test material to confirm the DSM data. Dispute resolutions in conflicting test data will be handled according to Section 23.	√	
9.7	Will provide OMEROS with a Certificate of Analysis for testing services performed at DSM. In the event that OMEROS is either performing or subcontracting release testing to an outside laboratory, DSM will release the product as defined in Section 17.		√
9.8	Will use appropriately validated/qualified analytical methods for routine Product testing. Will perform sterility and bacterial endotoxin testing at a minimum for parenteral products produced within DSM.		√
9.9	Any OOS occurrence identified will follow the DSM investigation process and procedures as defined in Section 15.		√
9.10	Will provide laboratory data package (agreed upon copies of relevant analytical data) with delivery dates subject to mutual agreement.		√
10 FINISH PRODUCT STABILITY			
10.1	OMEROS is responsible for review and approval of the stability agreement for the Products and DSM is responsible for executing stability programs in accordance with the approved stability agreement. The stability activities (contract storage, contract testing) will be defined in a separate stability agreement that will identify the storage requirements, testing responsibilities, testing specifications and methods, testing intervals, and bracketing, if applicable.	√	√
10.2	Any Out of Specifications ("OOS")/Out of Trend (OOT) or deviations occurrence that is confirmed according to the stability program will be promptly communicated to OMEROS and DSM shall provide assistance as required for regulatory reporting purposes. Any Out of Specification/Out of Trend or deviation occurrence identified will follow the DSM investigation process and procedures as defined in Section 15.		√
11 RETENTION OF SAMPLES			
11.1	DSM will retain API samples following procedures that are in accordance with applicable regulations.		√
11.2	Will retain excipient samples following procedures that are in accordance with regulations.		√
11.3	Will retain samples of the Products representing DSM operations for one (1) year beyond the expiry period. The amount of the sample to be retained will be at least twice (2 times) the quantity required to carry out all of the tests to verify that the material meets its specifications.		√

Responsibilities		OMEROS	DSM
11.4	Will retain a copy of any Product labeling containing Lot and expiration dating as part of the executed batch record.		√
11.5	Will notify OMEROS prior to destruction of any product at the completion of the retention period.		√
11.6	May designate materials to be shipped to a designated location beyond the DSM retention period.	√	
12 VALIDATION			
12.1	Responsible for providing product characterization data and critical product attributes to support design space and the commercial process validation requirements.	√	√
12.2	Responsible for ensuring that the product parameters are qualified and that the commercial manufacturing process is validated per established systems. The validation should ensure, with a high degree of certainty, that the process is capable of consistently achieving the Product's acceptance criteria.		√
12.3	Prepare a technical document outlining the development and transfer activities of any specified product(s) into DSM's facility.	√	√
12.4	Will ensure, via validation or verification that cleaning processes carried out on PRODUCT contact surfaces between batches of different products and raw materials are adequate to prevent contamination within the requirements outlines in quality policies. Data should be available to support the campaign of batches of the same product and the type of cleaning that will be performed in between manufacturing of the same product.		√
12.5	Will provide required information (i.e., LD50, toxicity, solubility, batch size, fill volume, product min dose/70Kg patient) to establish cleaning limits.	√	
12.6	Will provide any changes in dosing strategies, particularly smallest therapeutic and largest single dose prior to change in clinic or market to ensure cleaning limits justification remain applicable.	√	
12.7	Responsible for all laboratory, equipment, computer, facility, and utility qualification activities associated with the Products.		√
13 CALIBRATION/PREVENTATIVE MAINTENANCE			
13.1	Will maintain a calibration and preventative maintenance program to support the manufacturing, testing, packaging and storage of Products.		√
13.2	Shall maintain and follow a procedure that documents the actions to be taken in the event of a calibration failure.		√
13.3	Investigate deviations from approved standards of calibrations to determine if these deviations could have an impact on the quality of the Product and notify OMEROS as required per Section 15.		√
14 SUBCONTRACTING			
14.1	Any subcontracted laboratory or manufacturing facility for the Product must be approved by OMEROS prior to being used by DSM.		√
14.2	DSM will audit such subcontractors to determine compliance with cGMP according to DSM's criteria, which may differ from the criteria in the contractor quality agreement with OMEROS. Any discrepancies will be discussed with OMEROS.		√
15 INVESTIGATIONS			
15.1	Responsible for investigating any testing performed by DSM, or coordinating the investigation when testing done by a lab contracted by DSM that is confirmed as a failure to meet Product specifications (i.e. out of specification) and will follow internal procedures that are in accordance with regulatory guidelines.		√
15.2	Will support investigation request for any testing performed by OMEROS that is confirmed as a failure to meet Product specifications (i.e. out of specification) and will follow internal procedures that are in accordance with regulatory guidelines.		√

Responsibilities		OMEROS	DSM
15.3	Responsible for investigating any deviation from the process during manufacture and will follow internal procedures that are in accordance with regulatory guidelines.		√
15.4	Will notify OMEROS of any apparent Out of Specification (Product Testing Record) failures specific to Product within [†], i.e. excluding determinate laboratory errors. Will notify OMEROS within [†] of any deviation management record (DMR) initiated related to Product or process that impacts Omeros product.		√
15.5	As part of the written notification acknowledgement, OMEROS will confirm if they require approval of the specific record within [†] days. If no response is received, DSM will proceed to complete in the investigation without OMEROS approval. A copy of the closed investigation will be provided upon completion. If OMEROS approval is required on a specific investigation, OMEROS will provide investigation comments or approval within [†] days of investigation receipt.	√	√
15.6	As the Product license holder and technical Product/process expert provide technical and/or Product quality assessments in support of investigations, if required.	√	
15.7	Will notify OMEROS in the event that a Product or OMEROS provided material will be rejected.		√
15.8	Will notify OMEROS within [†] if any problems are discovered that may affect Product batches shipped in order to assure that regulatory reporting guidelines may be met.		√
16 BATCH DOCUMENTATION REVIEW			
16.1	Will provide a standard Certificate of Analysis indicating the test results performed by DSM as well as a signed Certificate of Compliance confirming that the Products have been manufactured, tested, and stored according to the requirements of the Master Production Record and cGMP criteria.		√
16.2	Will provide a list of any Product testing record, manufacturing deviation, and material deviation as part of the release documentation package.		√
16.3	Will provide complete batch documentation and analytical raw data related to only Assay and impurities for the [†] full scale batches/commercial batches. (Since [†] PV batches are full scale batches, only the data for the [†] full scale batches/commercial batches are needed to meet [†] batches.) Due to the request for additional documentation, the typical batch record review time period is being increased to [†] to allow for extra documentation review and processing.		√
16.4	With the commencement of commercial operations or before, perform evaluation to reduce required batch record copies. Changes to the release process for commercial batches may occur at any time with written agreement as defined in Appendix III.	√	√
17 PRODUCT DISPOSITION			
17.1	Responsible for release to commerce and further distribution of the Products once dispositioned by DSM for release.	√	
17.2	Will release the Product to OMEROS for shipment if all pre-defined release criteria are met, which may include OMEROS QA authorization for shipment.		√
17.3	OMEROS may, at its own discretion, reject a batch which DSM has dispositioned as satisfactory. However, the decision to reject shall not be based on a discrepancy between OMEROS and DSM's methodologies. Any problem discovered by OMEROS likely to cause rejection of the approved Products will be communicated to DSM within [†] days from receipt of the full release documentation package.	√	
17.4	Any disputes between the parties with respect to rejection of Product shall be resolved in accordance with Section 23 hereinafter.	√	√
18 STORAGE AND SHIPMENT			
18.1	Will store the Products under conditions specified by Product label requirements as supplied by OMEROS. Product storage areas will be continuously monitored.		√

Responsibilities		OMEROS	DSM
18.2	Will ensure that during storage before shipping of the Products, appropriate controls are in place to ensure that there is no interference, theft, product contamination, or mixture with any other products or materials. Will notify OMEROS any environmental outage within [†] days of becoming aware of the event and will follow the DSM investigation process and procedures as defined in Section 15 if Omeros product is affected.		√
18.3	Will provide details of any Product shipping requirements (i.e. labeling, container sealing and integrity, shipment monitoring, storage, and shipping conditions) based upon OMEROS' shipping qualification requirements.	√	
18.4	Label and package Product for transit pursuant to instructions provided in writing by OMEROS that comply with cGMP and other applicable regulations (e.g., OSHA, DOT).		√
18.5	Ship to the designated locations upon request from OMEROS. DSM will not ship any Product that is under quarantine unless according to controlled procedures which fully comply with regulatory requirements and which are mutually agreeable between DSM and OMEROS.		√
18.6	In the event that OMEROS requests DSM to ship Product in quarantine, then OMEROS shall supply DSM with a written certification stating, "Product will not be released to clinical trials or commerce until fully released."	√	
19 DOCUMENT RETENTION			
19.1	Shall maintain a program to assure electronic and hardcopy documents that support pharmaceutical manufacturing processes adhere to defined retention requirements, security, and controlled destruction in compliance with regulations.		√
19.2	Will retain batch production records for the Products for a minimum of [†] from the date of manufacture of each batch.		√
19.3	Will notify OMEROS prior to destruction of any executed records at the completion of the DSM retention period.		√
19.4	Will acknowledge destruction within [†] days by DSM procedures or coordinate the documents to be transferred to a designated location beyond the DSM retention period.	√	
20 REGULATORY SUBMISSIONS			
20.1	Responsible for ensuring all appropriate regulatory filings and import/export documentation are filed with regulatory agencies prior to shipment/human administration.	√	
20.2	Will provide a regulatory data summary package to support applicable to CMC documents and additional regulatory filings as negotiated in the Supply Agreement.		√
20.3	Will provide notification of the applicable Product registration changes to align DSM changes as defined in Section 1.	√	
20.4	Responsible for registering the facilities with the FDA and to maintain the registration data such that it is readily available. Will provide the information to OMEROS for the drug listing.		√
20.5	Responsible for drug listing of Products, including submitting applicable updates and/or Product labeling.	√	
20.6	Will prepare an Annual Product Review (APR) after commencement of commercial activities. The APR data analysis for the review period shall include, at a minimum, status of batches processed, status of product deviations/investigations/CAPA, trending of complaints, status of stability studies maintained by DSM, status of change controls, statistical trending of the finished product test results performed by DSM, status of vendors for those materials DSM responsible for, status of raw materials received, and a summary report of the product retain review. The report shall be provided within [†] from the end of the review period.		√
20.7	Will mutually agree upon the reporting period for the data analysis for the annually generated APR and subsequent changes may be implemented by written notification agreeable to both Quality Department representatives.	√	√

Responsibilities		OMEROS	DSM
20.8	Will provide a summary of changes applicable to CMC documents, along with revised documents and change control information, within thirty (30) calendar days of the anniversary of the US FDA approval of the application or thirty (30) calendar days after end date of mutually agreed annual report period (referred to as the annual report data package).		√
20.9	Responsible for completing final Product Quality Review and will notify DSM in the event that any issues potentially impacting DSM processes are discovered during the Product Quality Review. Will provide DSM with necessary information for DSM to conduct appropriate investigation and implement CAPA into DSM processes.	√	
21 COMPLAINTS			
21.1	Responsible for receiving all Product complaints and formally requesting investigation, when applicable. Notification is required to contain the following information for DSM to initiate a complaint investigation: Product(s) affected including name and strength, lot number (if available), description of the complaint, and source of the complaint.	√	
21.2	Any complaints received by DSM directly from a complainant (e.g. secondary packaging contractors, consumer, pharmacist) will be forwarded to OMEROS within [†].		√
21.3	Upon receipt of the complaint notice, will perform the investigation within [†] days following internal procedures that are in accordance with regulatory guidelines for activities that are part of DSM processing.		√
21.4	Responsible for investigating activities occurring outside of DSM's controls (i.e. administration of the product, shipping related, counterfeiting).	√	
21.5	OMEROS and DSM can mutually agree to expedite complaint investigations in the event of potential regulatory-related actions or other agreed upon investigational situations.	√	√
22 REGULATORY ACTIONS			
22.1	Responsible for filing and initiating any Product regulatory action (i.e. adverse event, field alert, withdrawal, recall) due to any defect considered sufficiently serious, with data and assistance provided by DSM. Will provide DSM with a copy of any DSM relevant regulatory correspondence related to regulatory actions, redacted as applicable, associated with the manufacturing or packaging of the Product by DSM.	√	
22.2	OMEROS shall be responsible for coordinating all necessary activities regarding the regulatory action taken. Accordingly, DSM and OMEROS agree to cooperate fully regarding any regulatory action and the Parties agree to keep each other advised, and to exchange copies of such documentation as may be required, to assure regulatory compliance.	√	√
22.3	OMEROS acknowledges and understands that DSM has significant regulatory obligations as manufacturer of the Product if there are any indications that regulatory action would be necessary. DSM has the responsibility to notify appropriate regulatory agencies if patient safety may be at risk as a result of a released batch being found to not meet filed specifications or whose safety, quality, identity, potency or purity (SQIPP) are in question as a result of a deviation. In the event that DSM has reason to believe that market action should occur regarding the Product, DSM will provide written notification to OMEROS prior to notifying the regulatory agency and as soon as practicably possible.		√
23 DISPUTE RESOLUTION			
23.1	In the event that a dispute arises regarding the non-conformity of a batch of the Products or regarding other matters, the senior management of the quality departments shall in good faith promptly attempt to resolve disputed issues. DSM shall be responsible for determining when a batch of Product is suitable for release to OMEROS and OMEROS may only dispute a batch of Product after DSM has released the Product to OMEROS.	√	√

Responsibilities		OMEROS	DSM
23.2	If the parties cannot reach agreement, the matter shall be resolved in accordance with dispute resolution provisions of the Supply Agreement.	√	√

* *

APPENDIX I: Product Listing

Product	DEVELOPMENT STAGE	
OMS302	**Transfer, Clinical Trial Material, Commercial**	

APPENDIX II: Company Contact Individuals

OMEROS Contacts

NAME/ TITLE	RESPONSIBILITY	CONTACT
[†]	Quality, Complaints, and Regulatory Affairs	[†]
[†]	Quality and Complaints	[†]
[†]	Quality	[†]
[†]	Manufacturing Project Management	[†]

DSM Contacts

NAME/ TITLE	RESPONSIBILITY	CONTACT
[†]	General Quality	[†]
[†]	Manufacturing Quality Assurance - Steriles and Biological Quality Assurance	[†]
[†]	Manufacturing Quality – Customer support for South Operations Products	[†]
[†]	Audits	[†]
[†]	Change Control	[†]
[†]	Complaints Regulatory Affairs	[†]
[†]	Account Management	[†]

Note: Routine contacts will be established and communicated through project management and subsequently commercial services group.

Appendix III: Batch Documentation Review

Batch Record Documentation (Initial to commercial launch)

- Certificate of Analysis - reporting the DSM testing results
- Certificate of Compliance - confirming that the Products have been manufactured, tested, and stored according to the requirements of the Master Production Record and cGMP criteria.
- Deviation(s) – report list indicating all product specific deviations (i.e. Product testing record, manufacturing deviation, material deviation).
- Complete copy of the batch documentation (Manufacturing Work Order, Filling Work Order, Packaging Work Order), and analytical raw data (Assay and Impurities) for review prior to DSM release for shipment. Note: The Test Data are available separate from the batch documentation.
- Will provide complete batch documentation and analytical raw data related to only Assay and impurities for the [†] full scale batches/commercial batches. (Since [†] PV batches are full scale batches, only the data for the [†] full scale batches/commercial batches are needed to meet [†] batches.)
- Upon OMEROS notification of review approval, DSM will release the batch making product available for shipment to OMEROS.

This process will occur for development/transfer batches and up to the commercial batches (not to exceed [†] as explained above).

Reduced Batch Record Review

- Certificate of Compliance
- Certificate of Analysis
- Deviation listing and associate reports
- Select pages of production batch record(s), environmental monitoring results and test data

Transfer and terms of the reduced record review and DSM shipment release program will be approved by OMEROS and DSM and documented in writing as an addendum to the quality agreement.

APPENDIX IV: Revision History

Version	Revisons/Changes
1.0	Original

ANNEX 4: REGULATORY SUPPORT

OMEROS is responsible for submitting the registration package for regulatory agency approval within a mutually agreed time from receipt of the package from DSM (data only package). DSM will provide standard regulatory support for Product to include:

- Annual product review (APR)
- Maintenance of site Drug Master Files as required to support Product production facilities
- Regulatory agency hosting for pre-approval inspections (PAI)

OMEROS is financially responsible for all non-standard regulatory support that DSM may provide upon OMEROS' request .

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

ANNEX 5: DEVELOPMENT WORK

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

ANNEX 6: APPROVED VENDORS

INGREDIENT	Supplier (Catalog No.)	UNAPPROVED VENDOR (yes or no)
[†]	[†] [†] [†] [†]	[†]
[†]	[†] [†] [†]	[†]
[†]	[†] [†] [†]	[†]
[†]	[†] [†]	[†]

Container & Closure	Supplier	UNAPPROVED VENDOR (yes or no)
Vial	[†] [†]	[†]
Stopper	[†] [†]	[†]
Overseal	[†] [†]	[†]

† DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

EXHIBIT 12.1

Omeros Corporation
Computation of Deficiency in the Coverage of Fixed Charges by Earnings Before Fixed Charges

	For the three months ended March 31, 2014	Year Ended December 31, 2013	2012	2011	2010	2009
			(in thousands)			
Earnings before fixed charges:						
Loss from continuing operations before income taxes	$ (16,642)	$ (39,796)	$ (38,444)	$ (28,546)	$ (29,251)	$ (21,089)
Add fixed charges	1,511	5,621	2,305	2,144	2,104	2,596
Add amortization of capitalized interest	—	—	—	—	—	—
Add distributed income of equity investees	—	—	—	—	—	—
Subtract capitalized interest	—	—	—	—	—	—
Loss before fixed charges	$ (15,131)	$ (34,175)	$ (36,139)	$ (26,402)	$ (27,147)	$ (18,493)
Fixed Charges:						
Interest expense	$ 515	$ 1,865	$ 1,355	$ 1,532	$ 1,328	$ 1,948
Amortization of debt expense and loss from extinguishment of debt	157	502	374	352	503	254
Estimate of interest expense within rental expense	839	3,254	576	260	273	394
Preference security dividend requirements of consolidated subsidiaries	—	—	—	—	—	—
Total fixed charges	$ 1,511	$ 5,621	$ 2,305	$ 2,144	$ 2,104	$ 2,596
Deficiency of earnings available to cover fixed charges	$ (16,642)	$ (39,796)	$ (38,444)	$ (28,546)	$ (29,251)	$ (21,089)

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: May 12, 2014

/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: May 12, 2014

/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 March 31, 2014, 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: May 12, 2014

/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 March 31, 2014, 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: May 12, 2014

/s/ Michael A. Jacobsen

Michael A. Jacobsen
Principal Financial and Accounting Officer