

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

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended June 30, 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

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**OMEROS CORPORATION**

(Exact name of registrant as specified in its charter)

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Washington  
(State or other jurisdiction of  
incorporation or organization)

91-1663741  
(I.R.S. Employer  
Identification Number)

201 Elliott Avenue West  
Seattle, Washington  
(Address of principal executive offices)

98119  
(Zip Code)

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

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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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>

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 August 5, 2014, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 33,995,840.

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## 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 Marketing Authorisation Application, or MAA, for OMS302, or Omidria™, in the European Union, or EU, in 2014, and our expectation of a decision on the MAA in late 2014;*
- our anticipation that we will begin U.S. commercial sales of Omidria in the fourth quarter of 2014;*
- our anticipation that we will initiate marketing and sales of Omidria, assuming approval of our MAA for Omidria by the European Medicines Agency, or EMA, and partnering in Europe, in the EU in the first half of 2015;*
- our plans for sales, marketing and distribution of Omidria in the U.S. and for partnering, sales, marketing and distribution in the EU and other international territories;*
- our expectation that we will enroll the first patient in our Omidria pediatric study in the latter part of the third quarter of 2014;*
- our ability to successfully complete our Phase 2 clinical trials for OMS824 and 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 Omidria and our product candidates;*
- 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 interest and principal payments on our outstanding notes;*
- 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 anticipation that we will rely on contract manufacturers to develop and manufacture Omidria and our product candidates 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 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 Omidria and our product candidates 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, products and product candidates;*
- our involvement in potential claims, legal proceedings and administrative actions, the expected course and costs 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 1A 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*

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[Table of Contents](#)

*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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[Table of Contents](#)

OMEROS CORPORATION  
FORM 10-Q FOR THE QUARTER ENDED June 30, 2014

INDEX

	<u>Page</u>
<b><u>Part I — Financial Information</u></b>	<u>3</u>
<u>Item 1. Financial Statements</u>	<u>3</u>
<u>Consolidated Balance Sheets as of June 30, 2014 (unaudited) and December 31, 2013</u>	<u>3</u>
<u>Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2014 and 2013 (unaudited)</u>	<u>4</u>
<u>Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2014 and 2013 (unaudited)</u>	<u>5</u>
<u>Notes to Consolidated Financial Statements (unaudited)</u>	<u>6</u>
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>12</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>19</u>
<u>Item 4. Controls and Procedures</u>	<u>20</u>
<b><u>Part II — Other Information</u></b>	<u>21</u>
<u>Item 1A. Risk Factors</u>	<u>21</u>
<u>Item 6. Exhibits</u>	<u>39</u>
<u>Signatures</u>	<u>40</u>

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[Table of Contents](#)

## PART I—FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2014	December 31, 2013
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,533	\$ 1,384
Short-term investments	35,927	12,717
Grant and other receivables	252	379
Prepaid expenses	1,110	251
Other current assets	146	86
Total current assets	38,968	14,817
Property and equipment, net	907	939
Restricted cash	679	679
Other assets	439	100
Total assets	\$ 40,993	\$ 16,535
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 5,085	\$ 2,329
Accrued expenses	5,476	3,944
Current portion of notes payable, net of discount	1,609	5,600
Total current liabilities	12,170	11,873
Notes payable, net of current portion and discount	30,761	14,898
Deferred rent	8,673	8,148
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Preferred stock, par value \$0.01 per share:		
Authorized shares—20,000,000 at June 30, 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 June 30, 2014 (unaudited) and December 31, 2013;		
Issued and outstanding shares—33,994,432 and 30,359,508 at June 30, 2014 (unaudited) and December 31, 2013, respectively	340	304
Additional paid-in capital	278,055	235,685
Accumulated deficit	(289,006)	(254,373)
Total shareholders' equity (deficit)	(10,611)	(18,384)
Total liabilities and shareholders' equity	\$ 40,993	\$ 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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenue	\$ 45	\$ 140	\$ 145	\$ 1,235
Operating expenses:				
Research and development	12,407	9,564	24,424	16,691
Selling, general and administrative	4,855	3,736	8,622	7,724
Total operating expenses	17,262	13,300	33,046	24,415
Loss from operations	(17,217)	(13,160)	(32,901)	(23,180)
Investment income	5	2	7	8
Interest expense	(939)	(589)	(1,611)	(1,176)
Other income (expense), net	160	155	(128)	267
Net loss	\$ (17,991)	\$ (13,592)	\$ (34,633)	\$ (24,081)
Comprehensive loss	\$ (17,991)	\$ (13,592)	\$ (34,633)	\$ (24,081)
Basic and diluted net loss per share	\$ (0.53)	\$ (0.48)	\$ (1.07)	\$ (0.89)
Weighted-average shares used to compute basic and diluted net loss per share	33,933,356	28,199,739	32,415,198	27,053,946

See notes to consolidated financial statements

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

(In thousands)

(unaudited)

	Six Months Ended June 30,	
	2014	2013
<b>Operating activities:</b>		
Net loss	\$ (34,633)	\$ (24,081)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on disposal of assets	(9)	—
Depreciation and amortization	164	145
Stock-based compensation expense	3,417	2,153
Non-cash interest expense	331	242
Warrant modification expense	452	41
Changes in operating assets and liabilities:		
Grant and other receivables	127	1,219
Prepaid expenses and other current and noncurrent assets	(1,064)	(72)
Accounts payable and accrued expenses	4,279	1,001
Deferred revenue	—	(970)
Deferred Rent	525	1,961
Net cash used in operating activities	<u>(26,411)</u>	<u>(18,361)</u>
<b>Investing activities:</b>		
Purchases of property and equipment, net	(2)	(89)
Purchases of investments	(58,844)	(19,617)
Proceeds from the sale and maturities of investments	35,634	22,101
Net cash provided by (used in) investing activities	<u>(23,212)</u>	<u>2,395</u>
<b>Financing activities:</b>		
Proceeds from issuance of common stock, net of offering costs	37,754	16,120
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	783	42
Net cash provided by financing activities	<u>49,772</u>	<u>16,162</u>
Net increase in cash and cash equivalents	149	196
Cash and cash equivalents at beginning of period	1,384	1,520
Cash and cash equivalents at end of period	<u>\$ 1,533</u>	<u>\$ 1,716</u>
<b>Supplemental cash flow information</b>		
Cash paid for interest	<u>\$ 1,188</u>	<u>\$ 778</u>

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 biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Derived from our proprietary PharmacoSurgery® platform, Omidria™ (phenylephrine and ketorolac injection) 1%/0.3%, our first drug product, was approved by the U.S. Food and Drug Administration (FDA) on May 30, 2014 for use during cataract surgery or intraocular lens replacement (ILR) to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. Our PharmacoSurgery platform, designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures, is based on low-dose combinations of FDA-approved 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. We have six 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 Omidria and each of our product candidates and our programs, we have retained all manufacturing, marketing and distribution rights.

We have begun marketing Omidria in the U.S. and expect to begin selling Omidria in the U.S. in the fourth quarter of 2014. In September 2013, we submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Omidria and we expect a decision on the MAA in late 2014. Assuming approval of our MAA for Omidria by the EMA and partnering in Europe, we anticipate the initiation of marketing and sales of Omidria in the European Union (EU) in the first half of 2015. In the 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 June 30, 2014 and for the three and six months ended June 30, 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 June 30, 2014, we had \$37.5 million in cash, cash equivalents and short-term investments. 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 interest and principal payments on our outstanding notes for at least the next 12 months.

## [Table of Contents](#)

### *Inventory*

Capitalization of costs as inventory begins when the product has received regulatory approval in the U.S. or the EU. We expense inventory costs related to product candidates as research and development expenses prior to regulatory approval in the respective territory. For Omidria, capitalization of costs as inventory began upon U.S. regulatory approval on May 30, 2014. We did not incur any Omidria inventory costs between May 31, 2014 and June 30, 2014.

### *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.

### *Recent Accounting Pronouncements*

In May 2014, the Financial Accounting Standards Board issued an Accounting Standards Update, or ASU, related to the recognition of revenue that supersedes the prior guidance. This standard clarifies the principles for recognizing revenue utilizing a five-step process. This standard must be applied retroactively to each prior reporting period presented, or retrospectively with the cumulative effect of applying the standard recognized in the period adopted. We have not evaluated the impact on the financial statements once this standard is adopted. This standard is effective for interim and annual periods beginning after December 15, 2016.

### **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 and six months ended June 30, 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:

	June 30,	
	2014	2013
Outstanding options to purchase common stock	6,814,963	5,308,861
Warrants to purchase common stock	609,016	609,016
Total	7,423,979	5,917,877

### **Note 3—Cash, Cash Equivalents and Investments**

As of June 30, 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 June 30, 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:

[Table of Contents](#)

June 30, 2014				
	Level 1	Level 2	Level 3	Total
(In thousands)				
<b>Assets:</b>				
Money-market funds classified as non-current restricted cash	\$ 679	\$ —	\$ —	\$ 679
Money-market funds classified as short-term investments	35,927	—	—	35,927
<b>Total</b>	<b>\$ 36,606</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 36,606</b>

  

December 31, 2013				
	Level 1	Level 2	Level 3	Total
(In thousands)				
<b>Assets:</b>				
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
<b>Total</b>	<b>\$ 13,609</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 13,609</b>

Cash held in demand deposit accounts of \$1.5 million and \$1.2 million is excluded from our fair-value hierarchy disclosure as of June 30, 2014 and December 31, 2013, respectively. There were no unrealized gains and losses associated with our short-term investments as of June 30, 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:

	June 30, 2014	December 31, 2013
(In thousands)		
Contract research	\$ 1,844	\$ 858
Employee compensation	1,368	1,346
Clinical trials	751	596
Consulting & professional fees	836	649
Other accruals	677	495
<b>Total accrued liabilities</b>	<b>\$ 5,476</b>	<b>\$ 3,944</b>

**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/

## [Table of Contents](#)

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 June 30, 2014, the remaining unamortized discount and debt issuance costs associated with the debt were \$2.0 million and \$312,000, respectively.

### **Note 7—Revenue**

Revenue recognized from grants and other sources is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands)			
Small Business Innovative Research Grants	\$ 45	\$ 140	\$ 145	\$ 265
Vulcan Inc.	\$ —	\$ —	\$ —	\$ 970
Total revenue	\$ 45	\$ 140	\$ 145	\$ 1,235

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 product candidates. We recorded revenue related to these grants of \$45,000 and \$140,000 for the three months ended June 30, 2014 and 2013, respectively, and \$145,000 and \$1.2 million for the six months ended June 30, 2014 and 2013, respectively. As of June 30, 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 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 June 30, 2014, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately \$60.2 million. The 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.

## [Table of Contents](#)

### *Contracts*

In June 2014, we entered into an agreement with Ventiv Commercial Services, LLC (inVentiv) for field sales representatives and related sales operation services for the commercial launch of Omidria in the U.S. As of June 30, 2014, we have paid the implementation fee of \$308,000 of which \$205,000 was recorded as selling, general and administrative expense. The remaining \$103,000 is recorded as a prepaid expense in the Consolidated Balance Sheet at June 30, 2014. As of June 30, 2014, we did not have any non-cancellable amounts due under the agreement other than the implementation fee. Beginning at the time of deployment of the sales force in August 2014, we will begin incurring a non-cancellable monthly fee of approximately \$300,000 for the first 12 months of services. We can terminate the agreement subsequent to the 18-month anniversary of the deployment date.

We have an agreement with Patheon Manufacturing Services LLC (Patheon) for the commercial supply of Omidria through December 31, 2015. Pursuant to the terms of the contract, we are required to provide a monthly, non-binding production forecast covering the term of the contract to Patheon. Upon submission of the monthly forecast, a portion of the forecast becomes a firm purchase commitment. In the event we do not purchase the quantities included in the firm purchase commitment, we would owe a cancellation fee.

### *Development Milestones and Product Royalties*

We have retained worldwide commercial rights to Omidria and all of our product candidates in our clinical and preclinical programs. We potentially owe certain development milestones and sales based royalties on commercial sales of certain product candidates 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.

During the first quarter of 2014, we incurred a milestone payment of \$200,000 to Helion Biotech ApS (Helion) related to the filing of an Investigational New Drug Application (IND) with the FDA for our mannan-binding lectin-associated serine protease-2 (MASP-2) program.

### *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. After deducting offering expenses and underwriter discounts of \$2.5 million, we received net proceeds from the transaction of \$37.8 million.

### *Warrants*

The following table summarizes our total outstanding warrants as of June 30, 2014, which have a weighted average exercise price of \$23.85:

<b>Outstanding At June 30, 2014</b>	<b>Expiration Date</b>	<b>Exercise Price</b>
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
<b>609,016</b>		

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 had 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 six months ended June 30, 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 exercisable for 133,333 shares, with exercise prices of \$20, \$30 and \$40 per share, respectively.

[Table of Contents](#)

**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 June 30, 2014, a total of 8,765,684 shares were reserved for issuance under our stock plans, of which 1,950,721 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. The following assumptions were applied to stock option grants during the periods ended:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Estimated weighted-average fair value	\$ 8.20	\$ 3.57	\$ 8.20	\$ 3.57
<b>Weighted-average assumptions</b>				
Expected volatility	80%	82%	80%	82%
Expected term, in years	5.9	5.5	5.9	5.5
Risk-free interest rate	1.88%	1.02%	1.88%	1.02%
Expected dividend yield	—%	—%	—%	—%

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Research and development	\$ 901	\$ 566	\$ 1,911	\$ 1,147
Selling, general and administrative	729	494	1,506	1,006
Total	\$ 1,630	\$ 1,060	\$ 3,417	\$ 2,153

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	166,750	11.73		
Exercised	(134,924)	5.80		
Forfeited	(186,166)	9.90		
Balance at June 30, 2014	6,814,963	\$ 6.42	6.71	\$ 74,811
Vested and expected to vest at June 30, 2014	6,582,978	\$ 6.32	6.63	\$ 72,938
Exercisable at June 30, 2014	4,496,727	\$ 4.94	5.62	\$ 56,014

At June 30, 2014, there were 2,318,236 unvested options outstanding that will vest over a weighted-average period of 2.2 years. Excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with these options is \$12.5 million.

## [Table of Contents](#)

### 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 biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Derived from our proprietary PharmacoSurgery® platform, Omidria™ (phenylephrine and ketorolac injection) 1%/0.3%, our first drug product, was approved by the U.S. Food and Drug Administration, or FDA, on May 30, 2014 for use during cataract surgery or intraocular lens replacement, or ILR, to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain. Our PharmacoSurgery platform, designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures, is based on low-dose combinations of FDA-approved 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. We have six 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 Omidria and each of our product candidates and our programs, we have retained all manufacturing, marketing and distribution rights.

#### *Products, Product Candidates and Development Programs*

In May 2014, the FDA approved Omidria for use during cataract surgery or ILR. We have begun marketing Omidria in the U.S. and expect to begin selling Omidria in the U.S. in the fourth quarter of 2014. We have developed our own internal sales and marketing management team and have entered into an agreement for a contract sales organization to call on surgeons, hospitals and ambulatory surgery centers in the U.S. We submitted a Marketing Authorisation Application, or MAA, to the European Medicines Agency, or EMA, in September 2013 seeking authorization to permit us to market and sell Omidria in the European Union, or EU, for use in patients undergoing ILR. In October 2013, the MAA for Omidria was validated by the EMA and we expect a decision on the MAA in late 2014. 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 the first half of 2015. We have discussed with the FDA and EMA the design for pediatric studies for Omidria. In 2014 we initiated a pediatric study for Omidria in the U.S. and we expect to enroll the first patient in this study in the latter part of the third quarter of 2014. If this study is successfully completed according to the FDA's written request, Omidria would be eligible for an additional six months of marketing exclusivity in the U.S.

In our pipeline we have a series of development programs targeting pain, inflammation, coagulopathies and disorders of the central nervous system, including the following six clinical-stage programs: (1) our lead phosphodiesterase 10, or PDE10, inhibitor OMS824 for the treatment of schizophrenia, which is in a Phase 2 clinical program, (2) our lead PDE10 inhibitor OMS824 for the treatment of Huntington's disease, which is in a Phase 2 clinical program, (3) our lead MASP-2 antibody OMS721, which is in a Phase 2 clinical program in patients with thrombotic microangiopathies, or TMAs, (4) our PharmacoSurgery product candidate OMS103 for reducing inflammatory pain following arthroscopic partial meniscectomy, which has completed one Phase 3 trial in patients undergoing this procedure, (5) our PPAR $\gamma$  program, in which three Phase 2 clinical trials are being conducted by our collaborators to evaluate a PPAR $\gamma$  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 candidate OMS201 for use during urological procedures, including uroendoscopic procedures, which completed a Phase 1/Phase 2 clinical trial in 2010 and is not currently in active clinical trials. Of these six clinical programs, we currently are focused on OMS824, OMS721, and OMS103.

OMS824 is in two Phase 2 clinical programs: we have completed a Phase 2a clinical trial in schizophrenia and are currently enrolling in a Phase 2 clinical trial for Huntington's disease. In addition, we are conducting an ongoing Phase 1 clinical program evaluating the safety, tolerability and pharmacokinetics of OMS824 as well as a clinical trial to evaluate target occupancy of OMS824 using PET scans by measuring the extent to which OMS824 binds to PDE10 in the brain. 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.

## Table of Contents

Our IND application to evaluate OMS721 in patients with complement-mediated TMAs was cleared by the FDA in April 2014. A Phase 2 clinical program is currently underway. OMS721 has received Orphan Drug designation for the prevention (inhibition) of complement-mediated TMAs.

OMS103, a PharmacoSurgery product candidate, 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.

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 product candidates 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 expenses and, prior to the point we receive approval in either the U.S. or the EU, 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 prior to product approval, 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 \$18.0 million and \$13.6 million for the three months ended June 30, 2014 and 2013, respectively and \$34.6 million and \$24.1 million for the six months ended June 30, 2014 and 2013, respectively. These losses have resulted principally from expenses incurred in connection with research and development activities, consisting primarily of manufacturing services, clinical trials and preclinical studies associated with our current product and product candidates. Compared to 2013, we expect our 2014 net losses to increase as we continue to add personnel for our anticipated growth and to prepare for the commercial launch of Omidria, to advance our clinical trials, and expand our research and development efforts. As of June 30, 2014, our accumulated deficit was \$289.0 million, total shareholders' deficit was \$10.6 million and we had \$37.5 million in cash, cash equivalents and short-term investments.

### **Results of Operations**

In May 2014, the FDA approved Omidria for use during cataract surgery or ILR. We began marketing Omidria in the U.S. in August 2014 and expect to begin selling Omidria in the U.S. in the fourth quarter of 2014. With respect to the EU, we do not expect to begin marketing Omidria until after we have received approval of our MAA by the EMA and secured a partner with European commercial operations. Assuming approval of Omidria by the EMA and partnering in Europe, we anticipate the initiation of EU marketing and sales of Omidria in the first half of 2015. Due to the above and our lack of history of Omidria sales, we are not able to estimate Omidria revenues.

## [Table of Contents](#)

### Revenue

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Small Business Innovative Research Grant	\$ 45	\$ 140	\$ 145	\$ 265
Vulcan Inc.	—	—	—	970
<b>Total Revenue</b>	<b>\$ 45</b>	<b>\$ 140</b>	<b>\$ 145</b>	<b>\$ 1,235</b>

Historically, our revenue has consisted of grant funding and revenue recognized in connection with funding from third parties. Other than these funding sources, we do not expect to receive revenue from our product candidates unless we receive regulatory approval and commercialize our product candidates or enter into collaborative agreements for the development and commercialization of our product and product candidates. We continue to pursue government and private grant funding as well as collaboration funding for our product candidates and research programs.

The decrease in revenue during the three months ended June 30, 2014 was due to a reduction of research activity on grant projects, resulting in lower revenue recognized from our NIH grants.

The decrease in revenue during the six months ended June 30, 2014 was primarily 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, and as of that date no further revenue remains to be recognized under the agreement. In addition, there was a decrease in revenue recognized from our NIH grants during the six months ended June 30, 2014 due to a reduction of research activity on grant projects resulting in lower revenue recognized from our NIH grants.

### 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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Direct external expenses:				
Clinical research and development:				
OMS824	\$ 3,141	\$ 1,583	\$ 6,760	\$ 2,318
OMS721	2,582	—	4,615	—
Omidria	1,334	1,428	2,473	2,315
OMS103	11	102	28	368
Other clinical programs	8	8	15	18
Total clinical research and development	7,076	3,121	13,891	5,019
Preclinical research and development	678	2,372	991	3,612
Total direct external expenses	7,754	5,493	14,882	8,631
Internal, overhead and other expenses	3,752	3,505	7,631	6,913
Stock-based compensation expense	901	566	1,911	1,147
<b>Total research and development expenses</b>	<b>\$ 12,407</b>	<b>\$ 9,564</b>	<b>\$ 24,424</b>	<b>\$ 16,691</b>

The increase in total research and development expenses during the three and six months ended June 30, 2014 compared to the same periods in the prior year was due primarily to higher clinical material manufacturing and clinical trial expenses related to our Phase 1 and Phase 2 clinical programs evaluating OMS824 for the treatment of schizophrenia and Huntington's disease, as well as higher clinical material manufacturing and clinical trial expenses related to our Phase 2 clinical trial evaluating OMS721 for the inhibition of TMAs. Additional increases in research and development expenses included higher

## [Table of Contents](#)

employee costs specifically related to our OMS824 and OMS721 programs and higher expense related to non-cash stock compensation. The non-cash stock compensation expense increased for the three and six months ended June 30, 2014 compared to the same periods in 2013 due to the grant of stock options during the third quarter of 2013 related to annual performance reviews and new hire grants during the second quarter of 2014. These increased expenses for the three and six months ended June 30, 2014 compared to the same period in 2013 were partially offset by lower preclinical activity on our PDE7 program. We expect our research and development expenses to increase in the near term as we continue to advance OMS824 and OMS721 through clinical development, initiate or continue pediatric and other studies for Omidria, 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 product candidates. 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 candidate as well as ongoing assessments of each program's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates 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 product candidates 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. 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 June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Selling, general and administrative, excluding stock-based compensation expense	\$ 4,126	\$ 3,242	\$ 7,116	\$ 6,718
Stock-based compensation expense	729	494	1,506	1,006
Total selling, general and administrative expenses	<u>\$ 4,855</u>	<u>\$ 3,736</u>	<u>\$ 8,622</u>	<u>\$ 7,724</u>

The increase in selling, general and administrative expenses during the three and six months ended June 30, 2014 was primarily due to sales and marketing costs related to our planned commercial launch of Omidria in the U.S. This increase was primarily due to employee costs related to hiring sales managers and the marketing team and an increase in sales and marketing preparation activity for Omidria in the 2014 period.

In June 2014, we entered into an agreement with Ventiv Commercial Services, LLC, or inVentiv, for field sales representatives and related sales support systems for the U.S. commercial launch of Omidria. Beginning at the time of deployment of the sales force in August 2014, we will begin making a non-cancellable monthly fee of approximately \$300,000 for the first 12 months of services. The agreement can be canceled subsequent to the 18-month anniversary of the deployment date. We expect our selling, general and administrative expenses to increase significantly in the near term due to the planned commercial launch of Omidria.

## [Table of Contents](#)

### *Interest Expense*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Interest expense	\$ 939	\$ 589	\$ 1,611	\$ 1,176

The increase in interest expense during the three and six months ended June 30, 2014 was due to a higher average balance on our note payable during the 2014 period due to our new loan agreement, or the Oxford/MidCap Loan Agreement, with Oxford Finance LLC, or Oxford, and MidCap Financial SBIC, LP, or MidCap, which we entered into in March 2014 and under which we increased the aggregate amount of our outstanding indebtedness by approximately \$12.7 million.

### *Other Income (Expense), Net*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
	(In thousands)		(In thousands)	
Other income (expense), net	\$ 160	\$ 155	\$ (128)	\$ 267

Other income (expense) principally includes rental income and costs associated with warrant modifications. Other income (expense) for the three months ended June 30, 2014 was primarily related to rental income and was consistent with the same period in the prior year. The change in other income (expense) during the six months ended June 30, 2014 is due to a warrant modification expense of \$452,000 in the first quarter of 2014, relating to our extension of the exercise period of warrants to purchase up to 197,478 shares of our common stock by six months.

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

As of June 30, 2014, we had \$37.5 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 intended 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 \$37.8 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 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, as stated above, we received \$37.8 million from the sale of our common stock in the public offering and \$12.7 million in incremental borrowings under the Oxford/MidCap Loan Agreement, both in March 2014. We believe that our existing cash, cash equivalents and short-term investments, together with potential product 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.

## [Table of Contents](#)

	Six Months Ended June 30,	
	2014	2013
(In thousands)		
<b>Selected cash flow data</b>		
Cash provided by (used in):		
Operating activities	\$ (26,411)	\$ (18,361)
Investing activities	(23,212)	2,395
Financing activities	49,772	16,162

*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 six months ended June 30, 2014, as compared to the same period in 2013 by \$8.1 million, primarily due to higher operating expenses leading to an increase in our net loss, which was offset by an adjustment for the non-cash increase in stock based compensation of \$1.3 million. These higher operating expenses were primarily due to sales and marketing costs related to our planned commercial launch for Omidria in the U.S., to higher clinical material manufacturing and clinical trial expenses related to our OMS824 and OMS721 clinical programs, and to higher employee costs. Other activities impacting the overall increase in net cash used in operating activities between the comparative periods was a \$992,000 increase in prepaid expenses and other current and noncurrent assets, offset by cash provided by a \$3.3 million increase in accounts payable and accrued expenses.

*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 fluctuations in cash flows to be important to the understanding of our liquidity and capital resources.

Net cash used in investing activities in the six months ended June 30, 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 to provide cash for operating activities.

*Financing Activities.* Net cash provided by financing activities in the six months ended June 30, 2014 was due primarily to the \$37.8 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, both of which occurred in March 2014. During the 2013 period, cash provided by financing activities was primarily due to the \$16.1 million we received in our registered direct offering in May 2013 in which we sold 3.9 million shares of common stock. During the period, from January 2014 to March 2014, we also paid \$1.5 million of principal on the then outstanding Oxford notes. For the six months ended June 30, 2013, no cash was used for principal payments on the Oxford notes as we amended the notes in December 2012 to provide for interest-only payments through December 31, 2013.

### *Funding Requirements*

Because of the numerous risks and uncertainties associated with the development and commercialization of Omidria and our product candidates, and to the extent that we may or may not enter into collaborations with third parties to participate in the development and commercialization of Omidria or one or more of our product candidates, 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 commercial success of Omidria in the U.S.;
- the commercial success of Omidria in the EU, if and when Omidria is approved for sale;
- 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 cost, timing and outcomes of the regulatory processes for our product candidates;
- the extent to which we raise capital by selling our stock or entering into other forms of financing including debt agreements;

## Table of Contents

- 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 the commercialization of Omidria and the continued advancement of our programs;
- 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 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 corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales. 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.

### *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 have used, and intend to continue 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 June 30, 2014.

## [Table of Contents](#)

### Contractual Obligations and Commitments

The following table presents a summary of our contractual obligations and commitments as of June 30, 2014:

	Payments Due Within				Total
	1 Year	2-3 Years	4-5 Years	More than 5 Years	
	(In thousands)				
Operating leases	\$ 3,669	\$ 8,133	\$ 8,507	\$ 39,896	\$ 60,205
Capital leases (principal and interest)	52	104	70	—	226
Notes payable (principal and interest)	5,284	24,512	9,192	—	38,988
Goods & Services	804	—	—	—	804
Total	<u>\$ 9,809</u>	<u>\$ 32,749</u>	<u>\$ 17,769</u>	<u>\$ 39,896</u>	<u>\$ 100,223</u>

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 June 30, 2014, the remaining aggregate non-cancelable rent payable under the initial term of the lease is approximately \$60.2 million.

In June 2014, we entered into an agreement with inVentiv for a field sales force and related sales operation services for the commercial launch of Omidria in the U.S. As of June 30, 2014, we did not have any non-cancellable amounts due under the agreement other than the implementation fee. Beginning at the time of deployment of the sales force in August 2014, we will begin incurring a non-cancellable monthly fee of approximately \$300,000 for the first 12 months of services. We can terminate the agreement subsequent to the 18-month anniversary of the deployment date.

We have an agreement with Patheon Manufacturing Services LLC, or Patheon, for the commercial supply of Omidria through December 31, 2015. We are required to provide a monthly, non-binding production forecast covering the term of the contract to Patheon. Upon submission of the monthly forecast, a portion of the forecast becomes a firm purchase commitment.

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 began on lots manufactured after the regulatory approval date for Omidria, which was May 30, 2014 in the U.S. We expense inventory costs related to product candidates 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

## [Table of Contents](#)

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 June 30, 2014, we had cash, cash equivalents and short-term investments of \$37.5 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 officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, as of June 30, 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 June 30, 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 if we are unable to commercialize Omidria successfully, our inability to generate significant revenue from the sales of Omidria would adversely impact our ability to achieve profitability.**

We are a biopharmaceutical company with one product approved by the FDA for commercial sale in the U.S., Omidria™ (phenylephrine and ketorolac injection) 1%/0.3% for use during cataract surgery or intraocular lens replacement, or ILR. Omidria was approved by the FDA on May 30, 2014 and we anticipate beginning commercial sales of Omidria in the fourth quarter of 2014. Consequently, we have not yet generated any revenue from any product sales to date. We may not be able to commercialize Omidria successfully for a number of reasons, including:

- a lack of acceptance of Omidria by physicians, patients, third-party payors and other members of the medical community;
- our limited experience in marketing, selling and distributing Omidria or any other product;
- our limited experience managing third-party commercial manufacturing of Omidria or any other product;
- our reliance upon one manufacturer of Omidria and a limited number of suppliers of the product's active pharmaceutical ingredients, excipients and packaging materials;
- reimbursement and coverage policies of government and private payors such as Medicare, Medicaid, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- the relative price of Omidria as compared to alternative options for maintenance of pupil size and reduction of postoperative ocular pain during cataract surgery or ILR;
- changed or increased regulatory restrictions in the U.S., EU and other foreign territories; and
- a lack of adequate financial or other resources to commercialize Omidria successfully.

If we are not able to commercialize Omidria successfully for these or other reasons, our ability to generate revenue from product sales and achieve profitability will be adversely affected and the market price of our common stock could decline significantly.

**Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.**

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

- the level of demand for Omidria;
- the extent to which coverage and reimbursement for Omidria is available from government and private third-party payors such as Medicare, Medicaid, insurance companies, group purchasing organizations, health maintenance organizations and other plan administrators;
- the timing, cost and level of investment in our sales and marketing efforts to support Omidria sales;
- the timing, cost and level of investment in our research and development activities involving Omidria and our product candidates; and
- the timing and cost of conducting required post-approval studies for Omidria and expenditures we will or may incur to acquire or develop additional technologies, products and product candidates.

In addition, from time to time, we may enter into collaboration agreements with other companies that may include commercial arrangements, development funding and/or significant upfront and milestone payments. Amounts earned from our collaboration agreements, if any, may be an important source of our revenues. Accordingly, our revenues may also depend on

## [Table of Contents](#)

commercial arrangements, development funding and the achievement of development and clinical milestones under collaboration and license agreements. These upfront and milestone payments may vary significantly from quarter to quarter and any such variance could cause a significant fluctuation in our operating results from one quarter to the next.

For these and other reasons, it is difficult for us to forecast accurately future profits or losses. As a result, it is possible that in some quarters our sales of Omidria and/or our operating results may not meet the expectations of securities analysts or investors, which could cause the trading price of our common stock to decline, perhaps substantially.

### **We cannot be certain that we will successfully commercialize any of our product candidates, even if we receive regulatory approval for our product candidates.**

We have invested a significant portion of time and financial resources in the development of our product candidates, in addition to the development and commercialization of Omidria. Our ability to generate revenues depends on the commercial success of our product candidates that may be approved, as well as Omidria, which in turn will depend on several factors, including our ability to:

- generate commercial sales 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 product candidates, if approved, 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, and maintain commercial manufacturing arrangements with third-party manufacturers, necessary to meet the commercial demand for a product.

If we fail to commercialize successfully product candidates 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, which would materially and adversely affect our business, financial condition and results of operations.

### **Omidria and our product candidates, if commercialized, may never achieve market acceptance.**

The commercial success of Omidria and our product candidates, if commercialized, will depend on, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community. If Omidria or our product candidates, if commercialized, fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, Omidria or any product candidate 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 commercialized 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 Omidria or any of our PharmacoSurgery product candidates, if commercialized, would be used may be significantly less than the total number of such procedures performed. If Omidria or our product candidates, if commercialized, 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 gain or increase market penetration with Omidria or our product candidates, if commercialized, our growth prospects would be significantly harmed.

**If we are unable to obtain adequate reimbursement from governments or other third-party payors for Omidria or any other approved product that we may develop, or if we are unable to obtain acceptable prices for Omidria or those**

## [Table of Contents](#)

### **approved 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, 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 any 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 third parties and could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our approved products to each payor. We can provide no assurances at this time regarding the cost-effectiveness and the amount, if any, or method of reimbursement for Omidria or any of our product candidates. Further, we can provide no assurance that the amounts, if any, reimbursed to surgical facilities for utilization of any of our surgery-related products, including Omidria, or product candidates or to surgeons for the administration and delivery of these products or product candidates will be considered adequate to justify the use of these products or product candidates.

There may be significant delays in obtaining reimbursement coverage for newly approved products, including Omidria, and we may not be able to provide data sufficient to be granted 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. Even if we receive reimbursement approval for a product, the initial rate at which the product will be reimbursed could be reduced or eliminated at some later time. 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, including Omidria, is inadequate in light of our development and other costs or is significantly delayed, our business could be materially harmed.

### **If we are unable to market and sell successfully Omidria or our product candidates, if approved, we may be unable to generate product revenue.**

Omeros has never sold, marketed or distributed any biopharmaceutical product. Developing a sales force for any product is expensive and time-consuming, and a delay in hiring and training a sales force, or difficulties managing a contract sales force, could impact the timing or effectiveness of any product launch. While we have entered into an agreement with inVentiv for a field sales force and related sales operation services for the U.S. commercial launch of Omidria, we do not have a sales force for any of our product candidates. Further, we have never operated or managed an internal or third-party sales force for any product. Factors that may inhibit our efforts to commercialize any approved products, including Omidria, 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;
- the inability of sales personnel to sell or promote any approved product(s) to adequate numbers of hospitals, surgery centers, physicians and/or pharmacists;
- our inability to develop and maintain, or access, adequate 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

## [Table of Contents](#)

- unforeseen costs and expenses associated with creating a sales and marketing organization.

If we are unsuccessful in building and managing a sales and marketing infrastructure internally or through a third-party partner for any approved product, we will have difficulty commercializing the product, which would adversely affect our business and financial condition.

In the EU, we plan to enter into partnerships for Omidria marketing and distribution 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. Even if we obtain approvals from relevant government authorities in one or more non-U.S. territories, we would not expect to see sales of Omidria in those territories if we are unable to enter into such agreements on terms acceptable to us, if at all, which could adversely affect our business and financial condition.

### **We are subject to extensive government regulation, including the regulations associated with approval for marketing of Omidria and our product candidates.**

Both before and after approval of any product, we, Omidria and our product candidates, 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 candidate; product recall or seizure; interruption of manufacturing or clinical trials; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties. 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.

Omidria is our only product approved by the FDA, and the FDA has not approved any of our product candidates 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 any of our product candidates on a timely basis, if at all.

The FDA may decide that our data are insufficient for approval of our product candidates and require additional preclinical, clinical or other studies or additional work related to chemistry, manufacturing and controls. As we develop our product candidates, 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 Omidria and our product candidates 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. If we are unable to resolve these or any other questions by the FDA, 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 product candidates 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 product candidates or may never obtain marketing approval.

Even if regulatory approval of a product candidate is obtained, such as Omidria in the U.S., 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 approved product. Even after approval, discovery of previously unknown problems with an approved 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 approved product. The realization of any of these risks could harm our business and operating results.

### **Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing Omidria or our product candidates internationally.**

We intend to have Omidria and our product candidates, if approved, marketed outside the U.S. In order to market Omidria or any of our product candidates, if approved, in the EU and many other non-U.S. jurisdictions, we must obtain

## [Table of Contents](#)

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 product candidates in any non-U.S. market. The regulatory approval procedure varies among countries and can involve additional testing and data review. The requirements governing marketing authorization, the conduct of clinical trials, pricing and reimbursement vary from country to country. The time required to obtain regulatory approval outside the U.S. may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval discussed in these “Risk Factors” and we may not obtain foreign regulatory approvals on a timely basis, or at all. 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 regulatory approval in one or more foreign jurisdictions for Omidria or any of our product candidates could harm our business.

We have submitted an MAA with the EMA for Omidria, which is currently under review. The EU regulatory process is subject to substantial agency discretion and risks, including those described elsewhere in these “Risk Factors.” The EMA may decide not to approve our application, or to require us to obtain additional data regarding Omidria and to resubmit our marketing application(s) in order to consider Omidria for approval, further delaying our ability to market and generate revenue from the sale of Omidria in the EU. If there are any negative decisions or delays in the regulatory process, the market price of our common stock could decline significantly.

### **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 Omidria or our product candidates that may compete with Omidria or our product candidates, when commercialized.**

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 good manufacturing practices, or GMPs, for outsourcing facilities 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 that prepare compounded formulations that are within the scope of our issued patents. Because these patent violations may be sporadic and dispersed, we may not easily be able to identify the violations. Such actions may hinder our ability to generate enough revenue to achieve profitability and adversely affect our margins.

### **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 June 30, 2014, we had an accumulated deficit of approximately \$289.0 million. We do not anticipate generating revenue from the sale of our first FDA-approved product, Omidria, until the fourth quarter of 2014 at the earliest and may incur additional losses depending upon the commercial success of Omidria, and cannot be certain that we will ever achieve profitability. We will continue to incur significant and increasing costs as we support the commercial launch of Omidria in the

## [Table of Contents](#)

U.S. and, if approved, in the EU and other foreign territories, as well as conduct additional research on our product candidates. 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 the additional capital needed to support the preclinical and clinical expenses of development and commercialization of our product candidates, to develop a market for Omidria and our product candidates, if approved, 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 and our product candidates, 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:

- continue the 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 product candidates targeting GPCRs;
- scale-up and produce clinical and commercial supplies of Omidria and our product candidates, and conduct clinical studies for Omidria and our product candidates, including for OMS103, OMS824, OMS721, and product candidates 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 product candidates;
- 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 product candidates 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 or complete all of the clinical trials in our Phase 3 clinical program for OMS103, which could prevent us from generating sales revenue for Omidria and/or OMS103, respectively. 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 commercialize Omidria and complete the clinical development and commercialization of our product candidates 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.

### **We have no capacity to manufacture clinical or commercial supplies of Omidria or our product candidates and intend to rely solely on third parties to manufacture clinical and commercial supplies of Omidria and our product candidates.**

We intend to rely on third party manufactures to produce commercial quantities of Omidria and any of our product candidates should they receive regulatory approval. Additionally, we intend to rely on third parties to produce clinical drug supplies need for clinical trials. With the exception of our agreements with Patheon 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 other product candidates, and can provide no assurance that we will be able to do so on commercially reasonable terms, if at all. Our agreement with Patheon for the commercial 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 Patheon’s relevant facility in the absence of an agreement with Patheon to transfer the manufacture of Omidria to an alternative Patheon facility. If we elect not to, or Patheon is unable or unwilling to, manufacture Omidria at Patheon’s planned alternative facility, or if our supply agreement with Patheon 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 Patheon manufacturing facility or a different manufacturer, or any significant delays in the timely completion of the transfer of the Omidria manufacturing process,

## [Table of Contents](#)

could materially harm our business and prospects. Any significant delays in the manufacture of clinical or commercial supplies of Omidria or our product candidates could materially harm our business and prospects.

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

Contract manufacturers that we select to manufacture Omidria or our product candidates 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 impact the commercialization of Omidria and our product candidates. 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 current good manufacturing practices, or GMPs, 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 product candidates, or establishing additional manufacturers for Omidria, 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 regulatory approval, product seizure or recall or withdrawal of product approval. If the safety of Omidria or any product candidate 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 Omidria or one or more of our product candidates, 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 Omidria or product candidates 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 the applicable product(s).

**Ingredients, excipients and other materials necessary to manufacture Omidria or our PharmacoSurgery product candidates may not be available on commercially reasonable terms, if at all, which may adversely affect the development and commercialization of Omidria or those PharmacoSurgery product candidates.**

We and our third-party manufacturers must obtain from third-party suppliers the active pharmaceutical ingredients, excipients and primary and secondary packaging materials necessary for our contract manufacturers to produce Omidria and our PharmacoSurgery product candidates for our clinical trials and, to the extent approved, for commercial distribution. Suppliers may not sell these ingredients, excipients or materials at the time they are needed 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, excipients and materials for Omidria and our PharmacoSurgery product candidates, we have not yet entered into agreements for the supply of all such ingredients, excipients or materials 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, excipients or materials in a timely manner or in the quantities required. If we or our third-party manufacturers are unable to obtain these active pharmaceutical ingredients, excipients and materials as necessary for the manufacture of commercial supplies of Omidria, our ability to generate revenue from the sale of Omidria would be materially and adversely affected. Further, if we or our third-party manufacturers are unable to obtain active pharmaceutical ingredients, excipients and materials as necessary for our clinical trials or for the manufacture of commercial supplies of our product candidates, if approved, potential regulatory

## [Table of Contents](#)

approval or commercialization would be delayed, significantly impacting our ability to develop and commercialize our product candidates, which would materially and adversely affect our ability to generate revenue from the sale of our product candidates.

**If our clinical trials are delayed, we may be unable to develop our product candidates on a timely basis, which will increase our development costs and delay the potential commercialization of our product candidates should they receive regulatory approval.**

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 candidate materials or other materials necessary to conduct our clinical trials;
- the need to qualify new suppliers of product candidate materials for FDA and foreign regulatory approval;
- an unfavorable 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 candidate. 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 Omidria or 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;

## Table of Contents

- 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 or 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 products or 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 product candidates.**

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 commercialize or obtain regulatory approval for our product candidates.

**We may need licenses for active ingredients from third parties to develop and commercialize some of our product candidates, which could increase our development costs and delay our ability to commercialize those product candidates.**

Should we decide to use active pharmaceutical ingredients in any of our product candidates 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 product candidates from these programs by either accessing or developing alternate active ingredients, resulting in increased development costs and delays in commercialization of these product candidates. 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 product candidates 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.**

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.

## [Table of Contents](#)

### **We have granted Vulcan a lien on all of our GPCR assets, excluding intellectual property, which 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 product candidates 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 product candidates 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 product candidates from our MASP-2 and Plasmin programs depends on third-party developers and manufacturers of biologic drug products.**

Any product candidate 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 candidate 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 product candidates that are suitable for clinical trials or that can be successfully commercialized or generate revenue through partnerships.**

Any product candidates 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

## [Table of Contents](#)

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 product candidates that are suitable for clinical testing. For example, we have not yet generated any products or product candidates from our GPCR program. We may discover that there are fewer druggable 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 product candidates that successfully complete preclinical or clinical testing. If we are unable to develop product candidates, potential corporate partners may be unwilling to enter into partnership agreements with us. We also cannot be certain that any product candidates that do advance into clinical trials will successfully demonstrate safety and efficacy in clinical trials. Even if we achieve positive results in early clinical trials, they may not be predictive of the results in later trials.

**Because we have a number of development programs and are considering a variety of product candidates, we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates 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 product candidates that we believe are the most promising. As a result, we may forego or delay the pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential and may not be able to progress development programs, including our GPCR program, as rapidly as otherwise possible. Our resource allocation decisions may cause us to fail to capitalize on viable potential commercial products or profitable market opportunities. Further, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that 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 and product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. 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

## [Table of Contents](#)

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 product candidates 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 or product candidates;
- 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 or product candidates 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 product candidates 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 or product candidate 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 and product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we, or our contract manufacturers, are infringing the third party's patents and would order us or our 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

## [Table of Contents](#)

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 and product candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we 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, product candidates, 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

## [Table of Contents](#)

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. Demopoulos, M.D., our president, chief executive officer and chairman of the board of directors. Losing the services of any key member of our management team, whether from death or disability, retirement, competing offers or other causes, 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

## [Table of Contents](#)

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 the market than Omidria or any future products that we may develop and commercialize. Our competitors also may market a product that proves to be unsafe or ineffective, which may affect the market for 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 candidate 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 Omidria or any other future 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 candidate for which we obtain marketing approval, such as Omidria, 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 candidate 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 Omidria or any of our other approved products, or failure to comply with regulatory requirements, may result in:

## Table of Contents

- 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 Omidria, or for our product candidates 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 and product candidates. In addition, product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to obtain and maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the commercialization of Omidria or our product candidates progresses, or that future claims against us will be covered by our product liability insurance. Further, our product liability 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 June 30, 2014, our stock traded as high as \$18.01 per share and as low as \$4.75 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:

- EMA actions related to our MAA submission for Omidria;
- FDA or foreign regulatory actions related to Omidria or any of our product candidates;
- 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 Omidria or any of our product candidates, 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 Omidria and our product candidates;
- 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

## Table of Contents

- 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 Omidria and our product candidates 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. 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 product candidates 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 9.4 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.

[Table of Contents](#)

**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 the sole source of potential gain for shareholders in the foreseeable future, and an investment in our common stock for dividend income should not be relied upon.

[Table of Contents](#)

ITEM 6. EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
10.1††	Master Services Agreement between Omeros Corporation and Ventiv Commercial Services, LLC, made as of May 12, 2014
10.2††	Project Agreement (Detailing and Sales Operation Services) between Omeros Corporation and Ventiv Commercial Services, LLC, made as of May 12, 2014
10.3	First Amendment to Project Agreement (Detailing and Sales Operation Services) between Omeros Corporation and Ventiv Commercial Services, LLC, dated June 13, 2014
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

†† Portions of this exhibit are redacted in accordance with a request for confidential treatment.

[Table of Contents](#)

**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: August 11, 2014

/s/ Gregory A. Demopulos

Gregory A. Demopulos, M.D.

President, Chief Executive Officer and Chairman of the Board of Directors

Dated: August 11, 2014

/s/ Michael A. Jacobsen

Michael A. Jacobsen

Vice President, Finance, Chief Accounting Officer and Treasurer

**MASTER SERVICE AGREEMENT**

This Master Service Agreement (this “Master Agreement”) is made as of May 12, 2014 (the “Effective Date”), by and between Ventiv Commercial Services, LLC, with an office located at 500 Atrium Drive, Somerset, NJ 08873 (“inVentiv”), and Omeros Corporation, with an office located at 201 Elliott Avenue West, Seattle, WA 98119 (“Client”). Client and inVentiv may each be referred to herein as a “Party” and collectively, the “Parties”.

**RECITALS**

- A. Client’s business includes the research, development and commercialization of pharmaceutical and biologic drug products.
- B. inVentiv and its Affiliates (as defined herein) offer a wide range of services and offerings to clients in the pharmaceutical and biotechnology arena.
- C. Client hereby engages inVentiv, and inVentiv hereby accepts such engagement, to provide various types of services pursuant to the terms hereof and each separate project agreement substantially in the form attached hereto as Annex A (each a “Project Agreement”) to be executed by duly authorized officers of each of the Parties. Except as otherwise mutually agreed, Client and inVentiv shall enter into a Project Agreement for each program pursuant to which inVentiv and its Affiliates offer services to Client.

**1. Interpretation and Construction**

(a) The Parties desire for the terms and conditions set forth in this Master Agreement to govern the relationship between the Parties. Each Project Agreement shall be subject to the terms of this Master Agreement. Subject to Section 12(b), unless otherwise expressly set forth in a Project Agreement, in the event of a conflict or inconsistency between the terms and conditions set forth in this Master Agreement and the terms and conditions set forth in a Project Agreement, the terms and conditions set forth in this Master Agreement shall take precedence, govern, and control.

(b) The Parties acknowledge that certain of inVentiv’s Affiliates may provide certain Services to Client in accordance with the terms of this Master Agreement and one or more Project Agreements executed hereunder between a particular inVentiv Affiliate and Client, subject to duly authorized officials of Client and the particular inVentiv Affiliate first executing the Project Agreement and such Project Agreement expressly confirming that the terms of this Master Agreement shall govern the relationship between Client and the particular inVentiv Affiliate, in which case the inVentiv Affiliate shall be bound to the same obligations and shall enjoy the same rights under this Master Agreement as does inVentiv, and Client and the particular inVentiv Affiliate shall be bound by the terms set forth in this Master Agreement. Client agrees that inVentiv acts solely on its own behalf and shall not be liable, or otherwise responsible, for the acts and/or omissions of any inVentiv Affiliate under any circumstances in connection with any Project Agreement that is not signed by inVentiv. Further, each inVentiv

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Affiliate acts solely on its own behalf and shall not be liable, or otherwise responsible, for the acts and/or omissions of inVentiv or any other inVentiv Affiliate under any circumstances in connection with this Master Agreement or any Project Agreement that is not signed by that inVentiv Affiliate. The term “Affiliate” means, with respect to any entity, any other entity directly or indirectly, through one or more intermediaries, controlling, controlled by or under common control with such entity. As used in this definition, the term “control” (including “controlled by” or “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity, whether through ownership of voting securities, as trustee, by contract or otherwise.

## **2. The Services**

(a) Client shall retain inVentiv to provide services as set forth in one or more Project Agreements (hereinafter the “Services”). The Services covered by this Master Agreement may include one or more of sales force automation, sample accountability, expense management, fleet services, national account management, detailing, sales operations support and other services as may be requested by Client and agreed to by inVentiv in one or more Project Agreements.

(b) Client has no obligation to inVentiv for Services under this Master Agreement in the absence of an executed Project Agreement covering such Services.

(c) Each Project Agreement shall allocate responsibility for project management and quality assurance activities necessary to perform the Services. inVentiv will provide regular updates as to the progress of the Services at a frequency and in a manner designated by the Parties in the Project Agreement.

(d) **Amendments to Project Agreements.** From time to time, it may be appropriate to make changes in or additions to a Project Agreement and the scope of Services or other matters specified therein. No such changes or additions shall be implemented, nor shall Client be obligated to pay for any additional Services, prior to the execution by the Parties of a written amendment (each, an “Amendment”) that refers to and amends the related Project Agreement. Any additional Services authorized pursuant to an Amendment shall be deemed to be Services under and shall be subject to this Master Agreement. When executed by both Parties, each Amendment shall be deemed incorporated into the related Project Agreement and this Master Agreement.

## **3. Representations and Warranties of the Parties**

(a) inVentiv represents, warrants and covenants that:

(i) it shall perform the Services in a professional manner in accordance with the standards of care and diligence regularly practiced by contract sales organizations in the biopharmaceutical industry contracting to provide the same or similar services and in accordance with those specifications which inVentiv and Client agree to (in writing) and any timelines agreed upon (in writing);

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(ii) it shall maintain in full force and effect all necessary licenses, permits, approvals (or waivers), and authorizations required by law to carry out its obligations under this Master Agreement and any Project Agreement;

(iii) the execution, delivery, and performance of this Master Agreement by inVentiv and the consummation of the transaction(s) contemplated hereby have been duly authorized by all requisite corporate action; that the Master Agreement constitutes the legal, valid, and binding obligation of inVentiv, enforceable in accordance with its terms (except to the extent enforcement is limited by bankruptcy, insolvency, reorganization, or other laws affecting creditors' rights generally and by general principles of equity); and this Master Agreement and performance hereunder does not violate or constitute a breach under any organizational document of inVentiv or any contract, other form of agreement, or judgment or order to which inVentiv is a party or by which it is bound;

(iv) the personnel assigned to perform Services rendered under this Master Agreement and any Project Agreement shall be capable professionally and duly qualified to perform the Services hereunder and in each Project Agreement;

(v) it is not a party to any agreement that would prevent it from fulfilling its obligations under this Master Agreement or any Project Agreement, and during the term of this Master Agreement or any Project Agreement it shall not enter into any agreement which would in any way prevent or materially restrict it from performing the Services under this Master Agreement or any Project Agreement; and

(vi) the Services shall be provided in compliance with (x) all applicable statutes, federal and state laws, ordinances, rules, or regulations of any governmental or regulatory authority including (but not limited to) the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the PhRMA Code on Interactions with Healthcare Professionals, the Accreditation Council for Continuing Medical Education requirements for continuing medical education, the American Medical Association Ethical Guidelines on Gifts to Physicians from Industry, the Federal Food, Drug and Cosmetic Act ("FDCA") and all applicable regulations and guidance promulgated pursuant thereto by the U.S. Food and Drug Administration, the Medicare/Medicaid anti-kickback statute, the Prescription Drug Marketing Act ("PDMA"), the Health Insurance Portability and Accountability Act, and all other federal, state and local laws, and rules, regulations, guidance, guidelines and requirements of all relevant governmental or regulatory authorities applicable to the marketing, promotion, distribution and sale of any pharmaceutical products in the United States, the Federal Trade Commission Act and all regulations and guidances promulgated by the U.S. Federal Trade Commission, the U.S. Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1, et seq., all as amended from time to time (collectively, "Applicable Law"); (y) any Client healthcare compliance policies in effect from time to time, copies of applicable ones of which will be provided to inVentiv prior to performance of Services under each Project Agreement and as may thereafter be updated from time-to-time during the course of performance of such Services; and (z) any applicable inVentiv policies and procedures.

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(vii) In performing the Services inVentiv shall take no action that will jeopardize the goodwill or reputation of Client or any product of Client.

(b) Client represents, warrants and covenants that:

(i) the execution, delivery and performance of this Master Agreement by Client and the consummation of the transaction(s) contemplated hereby has been duly authorized by all requisite corporate action; that the Agreement constitutes the legal, valid, and binding obligation of Client, enforceable in accordance with its terms (except to the extent enforcement is limited by bankruptcy, insolvency, reorganization or other laws affecting creditors' rights generally and by general principles of equity); and that this Master Agreement and performance hereunder does not violate or constitute a breach under any organizational document of Client or any contract, other form of agreement, or judgment or order to which Client is a party or by which it is bound;

(ii) Client shall act in good faith to provide inVentiv with the necessary materials, information, product training, and assistance, as specified in the applicable Project Agreement, reasonably required to enable inVentiv to perform the Services in compliance with all Applicable Law, and shall apply the degree of skill and care regularly practiced by pharmaceutical companies contracting to receive same or similar services to provide inVentiv (x) with the information and materials necessary for inVentiv to provide the Services and (y) if Client is required to provide deliverables under a Project Agreement, such deliverables will be sufficient for the purpose contemplated;

(iii) all content (product or otherwise), materials, documentation and information provided by it to inVentiv are in compliance with all Applicable Laws;

(iv) Client shall provide any and all reasonably required training for the relevant inVentiv Employees specifically regarding the Client product(s) and will be responsible for all costs and expenses of such training, including inVentiv personnel travel, lodging, and meals and others costs as agreed by the Parties;

(v) Client's products that are the subject matter of the Services provided under a Project Agreement shall be promoted under trademarks owned by or licensed to Client and are products which are either owned by Client and/or as to which Client has, or will have as of the date such product is marketed and sold, all material licenses, consents or approvals necessary pursuant to Applicable Laws to market and sell the products. Client represents and warrants that, to its knowledge, the trademarks, trade names and trade dress used in conjunction with such products do not infringe on any intellectual property rights of any other person or entity. Client further represents and warrants that to its knowledge the promotion of any Client product to be promoted by inVentiv does not infringe on any intellectual property rights of any other person or entity;

(v) it is not a party to any agreement that would prevent it from fulfilling its obligations under this Master Agreement and any Project Agreement, and during the term of this

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Master Agreement and any Project Agreement, it will not enter into any agreement which would in prevent or materially restrict inVentiv from performing the Services under this Master Agreement or any Project Agreement;

(vi) it is solely responsible for reviewing and approving Client's product promotional materials and literature and shall ensure all such materials provided to inVentiv for use in the Services shall comply with Applicable Law; and

(vii) Client shall notify inVentiv in the event that it becomes subject to a Federally Mandated Corporate Integrity Agreement (CIA) and such CIA requires inVentiv to provide Client with data, training, analysis, oversight or certifications that are not contemplated by the Services described herein. In such event, the Parties shall mutually agree on an appropriate allocation of costs and expenses associated with inVentiv's provision of such CIA related data, training, analysis, oversight or certifications not included in the scope of Services provided under this Master Agreement or any related Project Agreement.

#### **4. Independent Contractors; inVentiv Personnel**

(a) inVentiv and its directors, officers, employees and any persons providing the Services are at all times independent contractors with respect to Client. Persons provided by inVentiv to perform Services shall not be deemed employees of Client. Neither this Master Agreement nor the Services to be rendered hereunder shall for any purpose whatsoever or in any way or manner create any employer-employee relationship between inVentiv, its directors, officers, employees and any persons providing Services and Client. Client understands that inVentiv may utilize individual independent contractors in connection with its performance of the Services. inVentiv shall supervise, direct and govern the performance of such independent contractors in performing the Services and shall be responsible for such independent contractor's performance of such Services in accordance with this Master Agreement and applicable Project Agreement and shall be liable for the failure of any such independent contractor to perform the Services in accordance with this Master Agreement and applicable Project Agreement.

(b) inVentiv is, and at all times shall remain, solely responsible for the human resource and performance management functions of all inVentiv personnel provided to perform the Services, including any independent contractors utilized for such purpose. inVentiv shall be solely responsible and liable for all disciplinary, probationary, and termination actions taken by it, and for the formulation, content, and dissemination of all employment policies and rules (including written disciplinary, probationary, and termination policies) applicable to its employees, agents, and contractors including its individual independent contractors (individually, an "inVentiv Employee" and collectively, "inVentiv Employees").

(c) inVentiv shall obtain and maintain worker's compensation insurance and other insurances required for inVentiv Employees performing the Services and acknowledges that Client does not and shall not obtain or maintain such insurances, all of which shall be inVentiv's sole responsibility.

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(d) Except as otherwise set out in this Master Agreement or in a Project Agreement, Client shall have no responsibility to inVentiv or any inVentiv Employee for any compensation, expense reimbursements, benefits (including, without limitation, vacation and holiday remuneration, healthcare coverage or insurance, life insurance, pension or profit-sharing benefits, and disability benefits), payroll-related or withholding taxes, or any governmental charges or benefits (including, without limitation, unemployment and disability insurance contributions or benefits and workers compensation contributions or benefits) that may be imposed upon or be related to the performance by inVentiv or its employees, agents, or contractors of the obligations under this Master Agreement or any Project Agreement, all of which shall be the sole responsibility of inVentiv. To clarify, Client will not withhold any income tax or payroll tax of any kind on behalf of inVentiv.

(e) All employment decisions regarding an inVentiv Employee shall be made solely and exclusively by inVentiv and shall comply with inVentiv's human resource policies and procedures. Any request by Client for removal of an inVentiv Employee assigned to provide Service(s) shall be made in writing, supported by the Client's reasons for requesting the removal and by documentation of the inVentiv Employee's actions and/or behavior that support the request. In addition to any other actions inVentiv deems appropriate in the circumstances, inVentiv shall reassign such inVentiv Employee within thirty (30) days of receiving such request, so that such inVentiv Employee is no longer providing Services to Client.

(f) **Subcontractors.** Other than for individual independent contractors as provided for in Section 4(a) herein above, inVentiv may not subcontract any portion of the Services except with Client's prior written consent and approval of the subcontractor to be utilized in each instance (each a "Permitted Subcontractor"). Any approval of a Permitted Subcontractor by Client does not grant the right to any Permitted Subcontractor to further subcontract its obligations without first obtaining further express prior written consent of Client. Each Permitted Subcontractor shall be subject to, and inVentiv shall ensure that each Permitted Subcontractor is contractually obligated to comply with and does comply with, all obligations of inVentiv under this Master Agreement that apply to the subcontracted Services, provided that inVentiv shall remain responsible and liable for the performance of all of its obligations under this Master Agreement and for any breach thereof by any Permitted Subcontractor.

(g) **No Debarment.** inVentiv represents and warrants that it has not been debarred under the Generic Drug Enforcement Act, and covenants and agrees that it shall not employ or subcontract with any person or entity that has been so debarred to perform any Services under this Master Agreement or any Project Agreement. inVentiv shall promptly notify Client if during the term of this Master Agreement: (a) any regulatory agency takes action against inVentiv; (b) inVentiv becomes aware of the debarment or threatened debarment of inVentiv or any individual, corporation, partnership or association providing services to inVentiv in connection with this Master Agreement or any Project Agreement; or (c) inVentiv becomes aware of any other actual or anticipated event that is reasonably likely to have a material adverse effect on inVentiv's ability to perform the Services, including without limitation any material adverse change in inVentiv's financial condition. If inVentiv becomes aware of the debarment or threatened debarment of inVentiv or any individual, corporation, partnership or association providing

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services to inVentiv, inVentiv shall notify Client immediately and, in addition to any other rights or remedies Client may have, Client shall have the right to terminate this Master Agreement and any Project Agreement upon written notice without further cost or liability.

## 5. inVentiv Compensation

(a) In consideration of the performance of the Services in accordance with this Master Agreement and the applicable Project Agreement(s), Client shall pay inVentiv the fees, costs and expenses (collectively, the “Fees”) as set forth in each Project Agreement. inVentiv shall bill Client as set forth in each Project Agreement and invoices shall be sent by inVentiv to Client on a monthly basis for the Fees for Services.

(b) In addition to the Fees set forth in a Project Agreement, certain necessary and reasonable expenses will be charged to Client on a pass-through basis. These expenses will be billed to Client at actual cost incurred by inVentiv. Permitted pass-through costs shall be set forth in the applicable Project Agreement.

(c) Payments are due within thirty (30) days of Client’s receipt of each applicable invoice from inVentiv. If an invoice is not paid within thirty (30) days of Client’s receipt, inVentiv reserves the right to impose a finance charge of the lesser of one percent (1.0%) (calculated on a monthly basis) or the maximum amount permitted by law of all amounts due.

(d) In the event Client will be issuing purchase orders for payment of inVentiv invoices, Client shall issue such purchase orders in a timely manner in accordance with the terms and conditions set forth herein. The Parties understand and agree that all terms and conditions set forth in a purchase order are null and void, it being understood and agreed that this Master Agreement provides the terms and conditions governing the relationship between the Parties.

(e) **Invoices.** Invoices will reference the corresponding Project Agreement, and will include a description of the Services completed under the Project Agreement, an itemization of any costs provided for in the Project Agreement as a pass through expense item and a listing and receipt documentation for any authorized expenses, that are being charged in the invoice.

Invoices will be sent to Client by mail or e-mail addressed to the following or subsequently updated address:

Accounts Payable  
Omeros Corporation  
201 Elliott Avenue West  
Seattle, WA 98119  
ap@omeros.com

(f) **Obligation to Pay Taxes.** Any taxes that may be due and payable as a result of payments by the Client under this Master Agreement are solely inVentiv’s responsibility. Payments under this Master Agreement will be made in full in the agreed

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amounts without deduction for taxes of any kind whatsoever, in conformity with inVentiv's non-employee status. Notwithstanding the foregoing, if any payments made by Client under this Master Agreement are subject to withholding taxes under the laws of any relevant governmental entity, Client is authorized to withhold such taxes as are required under such laws and deduct such amounts from the amounts payable to inVentiv. In the event Client withholds such amounts, Client shall secure and use commercially reasonable efforts to deliver to inVentiv within five (5) business days of the applicable payment proof of any such taxes paid or required to be withheld.

## **6. Confidentiality**

(a) "Confidential Information" means any confidential or proprietary information, patentable or otherwise, in any form (written, oral, photographic, electronic or otherwise), that is disclosed by or on behalf of one Party (the "Disclosing Party") to the other Party (the "Receiving Party") in connection with this Master Agreement or any Project Agreement, whether prior to, on, or after the Effective Date; provided, however, that (x) the terms of this Master Agreement and any Project Agreement shall be considered the Confidential Information of both Parties (with each Party deemed to be the Receiving Party), and (y) all work product generated for Client by inVentiv in the course of performance of Services under this Master Agreement or any Project Agreement shall be deemed the Confidential Information of the Client (with inVentiv deemed to be the Receiving Party). Confidential Information includes, without limitation, technical, trade secret, commercial and financial information about either Party's (i) research or development; (ii) marketing plans or techniques, contacts or customers; (iii) organization or operations; (iv) business development plans (i.e., licensing, supply, acquisitions, divestitures or combined marketing); (v) products, licenses, trademarks, patents, other types of intellectual property or any other contractual rights or interests (including, without limitation, processes, procedures and business practices involving trade secrets or special know-how), (vi) pricing and financial information, and (vii) in the case of inVentiv, the names and contact information (i.e., phone number, address and e-mail address) of the inVentiv Employees. The Receiving Party shall neither use nor disclose Confidential Information received from the Disclosing Party for any purpose other than as specifically allowed by this Master Agreement or any Project Agreement.

(b) Each Party may disclose the other Party's Confidential Information to the extent that such disclosure is:

(i) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by the U.S. Securities Exchange Commission, or by the rules of any stock exchange upon which such Party's securities are listed or to which application for listing has been submitted; provided, however, that the Receiving Party shall first have given the Disclosing Party notice and a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such

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order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued.

(ii) made by or on behalf of (A) if the Receiving Party is inVentiv, to its Affiliates, and its or their employees, directors, consultants, advisors or representatives; or (B) if the Receiving Party is Client, to its Affiliates, and its or their employees, directors, consultants, advisors or representatives in each case ((A) and (B)) as may be reasonably necessary or useful in connection with the performance of such Party's obligations or exercise of its rights as contemplated by this Master Agreement or any Project Agreement; provided, however, that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the Receiving Party pursuant to this Section 6. The Receiving Party shall be liable to the Disclosing Party for any breach by any of such recipients of the restrictions set forth in this Section 6.

(c) Upon the expiration or termination of this Master Agreement and receipt of Disclosing Party's written request, Receiving Party, at its option, shall promptly either (i) return to the Disclosing Party all tangible forms of Confidential Information in its possession, including any and all copies (including electronic) and/or derivatives of Confidential Information made by either Party or their employees as well as any writings, drawings, specifications, manuals or other printed or electronically stored material based on or derived from, Confidential Information, or (ii) destroy Confidential Information in its possession and deliver to Disclosing Party a certification that such destruction has occurred; provided however, that Receiving Party may retain a copy of any information, including Confidential Information, that (x) the Receiving Party reasonably believes is required to comply with Applicable Law or to effectuate the Purposes of this Master Agreement, including any Project Agreement or (y) any computer records or files containing such Confidential Information that have been created solely by such Receiving Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such Receiving Party's standard archiving and back-up procedures, but not for any other uses or purposes. All such retained Confidential Information shall remain subject to the applicable confidentiality obligations of this Section 6. Except as expressly permitted herein, the Receiving Party shall not disclose to third parties any Confidential Information or any reports, recommendations, conclusions or other results of work under this Master Agreement or any Project Agreement without prior consent of an officer of the Disclosing Party. The obligations set forth in this Section 6, including the obligations of confidentiality and non-use, shall be continuing and shall survive the expiration or termination of this Master Agreement and any Project Agreement and will continue for a period of ten (10) years from the date of such expiration or termination.

(d) The obligations of confidentiality and non-use set forth herein shall not apply to the following, in each case as established by the Receiving Party: (i) Confidential Information at or after such time as it is or becomes publicly available through no fault of the Receiving Party; (ii) Confidential Information that is already independently known to the Receiving Party at the time of disclosure by the Disclosing Party, as shown by prior written records; (iii) Confidential Information at or after such time that it is disclosed to the Receiving Party by a third party with

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the legal right to do so; or (iv) Confidential Information that is independently developed by or for the Receiving Party without reference to the Disclosing Party's Confidential Information.

## **7. Restrictions on Solicitation**

(a) Except as expressly authorized under any Project Agreement, neither Party may solicit the employees or independent contractors of the other Party to become employees of, or consultants to, the other Party during the Term of this Master Agreement and any Project Agreement and for a one (1) year period following the termination of both this Master Agreement and any Project Agreement. The provisions of this Section 7 shall not apply with respect to either Party's employees or independent contractors who seek employment from the other Party on their own initiative, such as, but not limited to, in response to a Party's general vacancy announcement or advertisement.

(b) Client agrees during the Term of this Master Agreement and for one (1) year thereafter not: (i) to provide any contact information (including name, address, phone number or e-mail address) of any current inVentiv Employee to any third party which provides or proposes to provide Client with the same services being provided by inVentiv pursuant to a Project Agreement with the intent that such third party hire or retain such current inVentiv Employee, or (ii) to knowingly assist actively in any other way such a third party in employing or retaining such current inVentiv Employee that provides Services to Client under a Project Agreement.

(c) Client shall pay to inVentiv or cause the third party to pay to inVentiv, as the case may be, [†] for each current inVentiv Employee so employed or retained by Client or a third party due to a breach by Client of Section 7(a) or 7(b) as liquidated damages for breach of Sections 7(a) and 7(b).

(d) inVentiv shall pay to Client or cause the third party to pay to Client, as the case may be, [†] for each current employee of Omeros so employed or retained by inVentiv due to a breach by inVentiv of Section 7(a) as liquidated damages for breach of Section 7(a).

(e) The Parties acknowledge and agree that the remedies set forth in Sections 7(c) and 7(d) shall be the sole remedy for the breach of Section 7(a) unless otherwise agreed by the Parties. Each Party agrees that the provisions of such Section 7(c) and 7(d) represent a good faith estimate of the loss expected to be suffered by such Party as a result of such breach. For the avoidance of doubt, neither Party may terminate this Master Agreement in accordance with Section 12(a)(ii) for a breach of Section 7(a) if such breaching Party pays the applicable amount(s) set forth in Section 7(c) or 7(d).

## **8. Indemnification**

(a) inVentiv shall indemnify and hold Client, its Affiliates and its and their officers, directors, agents and employees harmless from and defend them against any and all liabilities, losses, proceedings, suits, actions, damages, claims or expenses of any kind, including court

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costs and reasonable attorneys' fees (collectively, "Losses") arising from the claim of a third party (including inVentiv Employees with respect to claims under Section 8(a)(iii)) that arise from: (i) any negligent acts or omissions by or the willful misconduct of inVentiv, its agents, directors, officers, or employees (including any inVentiv Employee), (ii) any material breach of any obligation under this Master Agreement or any Project Agreement, or material breach of any representation, warranty or covenant under this Master Agreement or any Project Agreement, in each case by inVentiv, its agents, directors, officers or employees, (iii) any claim that Client was in an employer/employee relationship with any inVentiv Employee(s) at the time of performance of the Services, and any related violation of applicable federal, state, or local statutes, laws, ordinances, regulations or guidelines relating to (A) employment; (B) safety and health; and (C) the payment of taxes and required taxes and payments with respect to employees ("Employment Law") with respect to any inVentiv Employee, including any claim brought by or on behalf of an inVentiv Employee for failure to pay wages or benefits; provided, however, that this clause (iii) shall not apply to any such Losses that arise or are alleged to arise from any liability of Client to an inVentiv Employee under the terms of any Client-sponsored benefits plans, programs or arrangements, or any Client-sponsored bonus, stock option, stock purchase, incentive, deferred compensation, supplemental retirement, severance or other similar compensation plans, programs or arrangements or (iv) any claim arising from the acts or omissions of any inVentiv Employee performing Services, including without limitation the practice or use of any third party's intellectual property, except to the extent such act or omission was taken at the specific direction of Client or was required by this Master Agreement or any Project Agreement hereunder.

(b) Client shall indemnify and hold inVentiv, its Affiliates and their respective officers, directors, agents, and employees harmless from and defend against any and all Losses arising from the claim of a third party that arise from: (i) any negligent acts or omissions by or the willful misconduct of Client, its agents, directors, officers, or employees, (ii) any material breach of any obligation under this Master Agreement or any Project Agreement, or material breach of any representation, warranty or covenant under this Master Agreement or any Project Agreement, in each case by Client, its agents, directors, officers or employees, (iii) any product liability claims related to products sold by Client using the Services of inVentiv, whether arising out of warranty, negligence, strict liability (including manufacturing, design, warning, or instruction claims) or any other product based statutory claim, and (iv) any intellectual property infringement claims relating to any trademarks owned by or licensed to Client.

(c) In case any action, proceeding or claim shall be brought against one of the Parties hereto (an "Indemnified Party") based upon any of the above claims and in respect of which indemnity may be sought against the other Party hereto (the "Indemnifying Party") such Indemnified Party shall promptly notify the Indemnifying Party in writing as soon as reasonably practicable. The failure by an Indemnified Party to notify the Indemnifying Party of such Claim shall not relieve the Indemnifying Party of responsibility under this Section, except to the extent such failure adversely prejudices the ability of the Indemnifying Party to defend such claim. The Indemnifying Party, at its expense and with counsel of its own choice reasonably acceptable to the Indemnified Party, shall defend against, negotiate, settle or otherwise deal with any such claim, provided that the Indemnifying Party shall not enter into any settlement or compromise of any claim which could lead to liability or create any financial or other obligation on the part of

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the Indemnified Party without the Indemnified Party's prior written consent. The Indemnified Party may participate in the defense of any claim with counsel of its own choice and at its own expense. The Parties agree to cooperate fully with each other in connection with the defense, negotiation, or settlement of any such claims. In the event that the Indemnifying Party does not undertake the defense, compromise, or settlement of any claim, the Indemnified Party shall have the right to control the defense or settlement of such claim with counsel of its choosing.

(d) Subject to Section 8(a), Client shall reimburse inVentiv for all reasonable, documented out-of-pocket expenses incurred by inVentiv in connection with responses to subpoenas and other similar legal orders issued to inVentiv in respect to Client's product or the Services performed under this Master Agreement and the applicable Project Agreement.

## **9. Limitation of Liability**

Except in the case of (a) gross negligence or willful or knowing misconduct (b) a breach of the obligations set forth in Section 6 (Confidentiality), neither Party shall be liable to the other Party with respect to any subject matter of this Master Agreement or any Project Agreement under any contract, tort, negligence, strict liability, breach of warranty (express or implied) or other theory for any indirect, incidental, special, punitive, exemplary or consequential damages, even if advised of the possibility of such damages. For clarification, this limitation shall not apply to the Parties' indemnification obligations set forth in Section 8 above. In addition, except for any liability arising from inVentiv's (i) gross negligence or willful or knowing misconduct or (ii) breach of its obligations set forth in Section 6 (Confidentiality), the total liability of inVentiv to Client resulting from the performance of the Services set forth in this Master Agreement and in any one or more Project Agreements between the Parties shall be limited to [†] the total fees actually paid by Client, and in no event less than [†] the fees that would have been paid by Client, to inVentiv for Services under the specific Project Agreement giving rise to the claim(s). For clarification, this limitation shall not apply to the Parties' indemnification obligations set forth in Section 8 above.

## **10. Intellectual Property; Ownership**

(a) Except as set forth in Section 10(b) below, all documents, materials, reports and deliverables provided by inVentiv to Client pursuant hereto, whether or not patentable, copyrightable, or susceptible to any other form of legal protection, which are made, conceived, reduced to practice, or authored by inVentiv or inVentiv's employees, representatives, or agents (if any) as a result of the performance of Services, or which are derived from use or possession of Client's Confidential Information (collectively, the "Deliverables"), shall be the sole and exclusive property of Client. Each Deliverable constituting an original work shall be considered a work made for hire under applicable copyright laws. Subject to Section 10(b) below, inVentiv hereby assigns and agrees to assign to Client all right, title, and interest in all worldwide intellectual property rights in the Deliverables, including, without limitation, patents, copyrights, and trade secrets.

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(b) Notwithstanding anything to the contrary set forth herein, to the extent any Deliverable or work made for hire includes inVentiv's concepts, ideas, models, know-how, software, methodologies, technology, techniques, procedures, management tools, workshops, manuals, macros, data files, inventions, and other intellectual capital and property that inVentiv has developed, created or acquired prior to or independent of performing Services under this Master Agreement (the "inVentiv Materials"), inVentiv shall retain exclusive ownership in such inVentiv Materials to that extent. inVentiv hereby grants Client a perpetual, non-exclusive, non-transferable (except in conjunction with the permitted assignment of this Master Agreement), royalty-free right and license, with the right to sublicense to a licensee or contractor, for it to use the inVentiv Materials solely in connection with its use of the Deliverables created by inVentiv in connection with the Services.

(c) Notwithstanding subsections (a) and (b) of this Section 10, unless otherwise expressly set forth in any Project Agreement, if any Deliverable incorporates any know-how or other intellectual property owned or controlled by a third party, then inVentiv shall use commercially reasonable efforts to acquire on behalf of Client a perpetual, royalty-free, world-wide, irrevocable, non-exclusive license or sublicense, with the right to sublicense to a licensee or contractor, to use such Deliverable. If, despite such efforts, inVentiv is unable to obtain such rights from such third party, then inVentiv shall, at its own cost and expense, generate a replacement Deliverable reasonably acceptable to Client that does not incorporate such third party know-how or other intellectual property.

## **11. Term**

The Agreement shall be in effect as of the Effective Date and shall remain in effect until the third anniversary of the Effective Date (the "Term") or until such later date as may be set forth in a Project Agreement (it being understood that this Master Agreement will not terminate in the event the term set forth in a Project Agreement is longer than the term set forth herein). The Parties may extend this Master Agreement for additional periods of one year each (each an "Additional Term") by mutual written agreement not less than sixty (60) days prior to the end of the then current term.

## **12. Termination**

(a) This Master Agreement and any Project Agreement may be terminated by inVentiv or Client as follows:

(i) inVentiv may terminate this Master Agreement and any or all Project Agreements upon written notice if any undisputed payment to be made to inVentiv by Client is not made when due and such overdue payment is not made within twenty (20) days from the date of written notice, in accordance with the requirements of Section 14(i) of the Master Agreement, from inVentiv to Client of such nonpayment and intent to terminate; provided, however, that before inVentiv sends such notice to Client, inVentiv will contact Client by telephone, within the first five (5) days following the date on which the undisputed amount owed was due to inVentiv, to ascertain the status of the payment.

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(ii) either Party may terminate this Master Agreement or any or all Project Agreements immediately upon written notice to the other Party, in the event that such other Party (or its Affiliate) has committed a material breach of this Master Agreement or any Project Agreement and such breach has not been cured within thirty (30) days of receipt of written notice from the non-breaching Party of such breach (provided that, during the thirty (30) day cure period for termination due to breach, each Party will continue to perform its obligations under the applicable Project Agreement);

(iii) either Party may terminate this Master Agreement or any or all Project Agreements immediately upon written notice to the other Party, in the event such other Party is either debarred from federal contracting or is a "Sanctioned Entity". For purposes hereof, a Sanctioned Entity is an entity that:

(A) Is currently under indictment or prosecution for, or has been convicted (as defined in 42 C.F.R. § 1001.2) of: (1) any offense related to the delivery of an item or service under the Medicare or Medicaid programs or any program funded under Title V or Title XX of the Social Security Act (the Maternal and Child Health Services Program or the Block grants to States for Social Services programs, respectively); (2) a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service; (3) fraud, theft, embezzlement, or other financial misconduct in connection with the delivery of a health care item or service; (4) obstructing an investigation of any crime referred to in (1) through (3) above; or (5) unlawful manufacture, distribution, prescription, or dispensing of a controlled substance; or

(B) Has been required to pay any civil monetary penalty regarding false, fraudulent, or impermissible claims under, or payments to induce a reduction or limitation of health care services to beneficiaries of, any state or federal health care program, or is currently the subject of any investigation or proceeding which may result in such payment; or

(C) Has been excluded from participation in the Medicare, Medicaid, or Maternal and Child Health Services (Title V) program, or any program funded under the Block Grants to States for Social Services (Title II) program; or

(iv) either Party may terminate the Master Agreement or any or all Project Agreements immediately upon written notice to the other Party in the event that such other Party has become insolvent or has been dissolved or liquidated, filed or has filed against it, a petition in bankruptcy and such petition is not dismissed within sixty (60) days of the filing, makes a general assignment for the benefit of creditors; or has a receiver appointed for a substantial portion of its assets.

(v) Client may terminate the Master Agreement or any or all Project Agreements for any reason or no reason upon ninety (90) days' written notice to inVentiv.

(vi) Client may terminate this Master Agreement or any or all Project Agreements immediately upon written notice if inVentiv enters into a merger, consolidation or similar transaction with any entity, or sells or transfers to any entity all or substantially all of its

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assets to which this Master Agreement or any Project Agreement relates, if at the time of such merger, consolidation, sale or transfer, such entity is developing or marketing (directly or indirectly) for its own account any product that is intended to compete with any product then under development or being commercialized by or on behalf of Client as identified on Annex B attached hereto, which may be amended unilaterally by Client from time to time upon written notice to inVentiv (such competitors, "Identified Competitors").

(vii) Either Party may terminate the Master Agreement or any or all Project Agreements upon written notice if the other Party has suspended performance in accordance with Section 14(d), and such suspension continues for sixty (60) days after the date of the occurrence.

(b) Each Project Agreement may be terminated in accordance with its own termination provisions, if any. In the event of any conflict in such termination provisions, the termination provisions contained in the applicable Project Agreement with respect to a party's right to terminate such Project Agreement and any consequences thereof shall govern. Except as set forth in this Master Agreement, the termination of any individual Project Agreement shall have no effect on the continued existence and enforceability of the Master Agreement or any other Project Agreement.

(c) Upon the effective date of such termination, the Parties shall have no further obligation to each other (other than those set forth in Sections 4, 6, 7, 8, 9, 10, 13 and 14 and this Section 12(c)), except that Client shall pay the amounts set forth or provided for in any Project Agreement for Services satisfactorily performed through the actual date of termination, including receipt of the relevant Deliverables; provided, however, that upon receipt of a notice of termination from Client, inVentiv shall use diligent efforts to mitigate and cancel, to the extent possible, all obligations that would incur expenses related to the Agreement or the terminated Project Agreement, including reassignment of any inVentiv employees previously assigned to perform the Services, as applicable, and inVentiv shall not, without Client's prior approval, perform any additional Services, incur expenses, or enter into any other obligations related to the Agreement or the terminated Project Agreement, as applicable.

### **13. Choice of Law; Dispute Resolution**

This Master Agreement and any Project Agreement shall be construed according to the laws of the State of New York (without reference to any principles regarding conflicts of laws). Before commencing any lawsuit, action or other proceeding regarding a dispute that arises between the Parties in connection with or relating to this Master Agreement or any Project Agreement ("Action"), the Parties agree to attempt to resolve such dispute through good faith negotiation during a period of 20 business days. Any Action brought by either Party shall be subject to the exclusive jurisdiction of the state and/or federal courts of New York, New York.

### **14. Miscellaneous**

(a) Each Party undertakes to maintain appropriate insurance in commercially reasonable amounts with financially capable carriers. In addition, Client shall carry product liability insurance in the amount of at least [†]. Neither Party's indemnity shall be capped by its

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insurance limits. Each Party shall name the other Party as an additional insured on all liability insurance coverage that is applicable to the Services being provided under one or more Project Agreements as their interests may appear. In addition, upon written request, each Party will provide the other with evidence of coverage complying with this Section. The Parties understand and agree that additional insurance requirements may be set forth in the Project Agreements.

(b) Each of the Parties acknowledges that the other Party may have no adequate remedy at law if it fails to perform any of its obligations under Section 6 of this Master Agreement, including as applied to any Project Agreement. In such event, each of the Parties agrees that the other Party shall have the right, in addition to any other rights it may have (whether at law or in equity), to pursue equitable remedies such as injunction and specific performance for the breach or threatened breach of any provision of such Section 6 from any court of competent jurisdiction. Both Parties agree to waive any requirement as to (i) posting a bond or other security as a condition for obtaining any such relief and (ii) showing irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 14(b) is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

(c) Neither inVentiv nor Client may assign or transfer this Master Agreement or any Project Agreement or any of its rights, duties or obligations hereunder without the other Party's prior written consent. Notwithstanding the foregoing, subject to Client's rights set forth in Section 12(a)(vi), either Party may assign all of its rights, duties and obligations under this Master Agreement or any Project Agreement without consent to any Affiliate or successor in interest (whether by merger, acquisition, asset purchase, stock purchase or otherwise) to all or substantially all of the business to which this Master Agreement or such Project Agreement relates; provided, however, that such acquiring party has sufficient financial resources reasonably to enable it to perform its obligations under such Master Agreement or Project Agreement, which it shall be deemed to have if it is publicly traded and has a total market capitalization of at least [†] at the time of such acquisition; and provided, further, that in the event such Party assigns one or more (but not all) Project Agreements then in effect to a third party pursuant to this Section, then the terms and conditions of this Master Agreement shall be deemed incorporated into such Project Agreements.

(d) The noncompliance of either Party with the obligations of this Master Agreement due to a state of force majeure, the laws or regulations of any government, regulatory or judicial authority, war, civil commotion, destruction of facilities and materials, fire, flood, earthquake, storm, failure of public utilities or common carriers, or any other similar causes beyond the reasonable control of the applicable Party shall not constitute a breach of contract, provided that such Party resumes performance as soon as possible following the end of the event that caused such noncompliance.

(e) If any provision of this Master Agreement is finally declared or found to be illegal or unenforceable by a court of competent jurisdiction, both Parties shall be relieved of all

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obligations arising under such provision, but, if capable of performance, the remainder of this Master Agreement shall not be affected by such declaration or finding.

(f) This Agreement, together with each applicable Project Agreement (including any attachments or exhibits hereunder or thereunder), contains all of the terms and conditions of the agreement between the Parties and constitutes the complete understanding of the Parties with respect thereto and supersedes all prior arrangements and understandings between Parties related to the subject matter hereof. Subject to Section 12(a)(vi), no modification, extension or release from any provision hereof shall be effected by mutual agreement, acknowledgment, acceptance of contract documents, or otherwise, unless the same shall be in writing signed by the other Party and specifically described as an amendment or extension of this Master Agreement.

(g) Neither Party shall make a public announcement regarding this Master Agreement or any Project Agreement, or the subject matter contained therein, without the prior written consent of the other Party (which consent may not be unreasonably withheld), except as may, in the reasonable opinion of the disclosing Party's legal counsel, be required by Applicable Law, including by the U.S. Securities Exchange Commission, or by any stock exchange upon which such Party's securities are listed or to which application for listing has been submitted, in which event the disclosing Party shall provide the other Party reasonable advance notice and review of any such disclosure to the extent practicable. Subject to the foregoing, neither Party may use the name of the other Party in connection with any public announcement without the other Party's prior written consent, provided, however, that in connection with its general marketing materials, a Party may list the name of the other Party in a non-descriptive fashion, in a list of the names of other similarly situated third parties that such Party does business with.

(h) This Agreement may be executed in any number of counterparts, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document.

(i) Any notices required or permitted under this Master Agreement shall be sent by overnight courier or first class, certified mail to:

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<b>To Client</b> <b>Address: Omeros Corporation</b> <b>201 Elliott Avenue West</b> <b>Seattle, WA 98119</b>	<b>To inVentiv</b> <b>Address:</b> Ventiv Commercial Services, LLC 500 Atrium Drive Somerset, NJ 08873 Attn: President
<b>Attention: General Counsel</b> <b>Fax: 206.676.5005</b>	<b>Attention:</b> <b>Fax:</b>
<b>Copy To: Accounts Payable (for notices regarding payment)</b>	<b>Copy To:</b> Ventiv Commercial Services, LLC 500 Atrium Drive Somerset, NJ 08873 Attn: VCS General Counsel

or to such other address or to such other person as may be designated by written notice given from time to time during the term of this Master Agreement by one Party to the other. Notices shall be deemed given upon receipt by the notified Party.

(j) Each of the Parties shall do, execute and perform and shall procure to be done and perform all such further acts, deeds, documents and things as the other Party may reasonably require from time to time to give full effect to the terms of this Master Agreement or any Project Agreement.

(k) Except as otherwise expressly provided in this Master Agreement, each Party shall pay its own expenses and costs incidental to the preparation of this Master Agreement and to the consummation of the transactions contemplated by this Master Agreement or each Project Agreement.

(l) Either Party’s failure to enforce any provision of this Master Agreement or any Project Agreement will not be considered a waiver of future enforcement of that or any other provision.

WHEREFORE, the Parties hereto have caused this Master Agreement to be executed by their duly authorized representatives as of the Effective Date.

**OMEROS CORPORATION**

By: /s/ Gregory A. Demopulos  
Name: Gregory A. Demopulos, M.D.  
Title: Chairman & CEO  
Date: 5/22/14

**VENTIV COMMERCIAL SERVICES, LLC**

By: /s/ Theodore Wong  
Name: Theodore Wong  
Title: VP & CFO  
Date: 5/13/14

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ANNEX A

**FORM OF PROJECT AGREEMENT**

This Project Agreement (the “PA”) is made as of \_\_\_\_\_, 2013, by and between VENTIV COMMERCIAL SERVICES, LLC, with its principal office located at 500 Atrium Drive, Somerset, New Jersey 08873 (“inVentiv”), and OMEROS CORPORATION, with its principal office located at 201 Elliott Avenue West, Seattle, Washington 98119 (“Client”). Client and inVentiv may each be referred to herein as a “Party” and collectively, the “Parties”.

**RECITALS**

- A. Client and inVentiv have entered into a Master Services Agreement dated as of \_\_\_\_\_, 2013 (the “Agreement”).
- B. Client and inVentiv desire to enter into this Project Agreement (the “PA”).

**[ ALTERNATE LANGUAGE FOR USE WITH INVENTIV AFFILIATES**

This Project Agreement (the “PA”) is made as of \_\_\_\_\_, 2013, by and between (NAME OF INVENTIV AFFILIATE), with its principal office located at 500 Atrium Drive, Somerset, New Jersey 08873 (“COMPANY”), and OMEROS CORPORATION, with its principal office located at 201 Elliott Avenue West, Seattle, Washington 98119 (“Client”). Client and COMPANY may each be referred to herein as a “Party” and collectively, the “Parties”.

**RECITALS**

- A. Client and Ventiv Commercial Services, LLC, an Affiliate of COMPANY, have entered into a Master Services Agreement dated as of \_\_\_\_\_, 2013 (the “Agreement”).
- B. Client and COMPANY desire to enter into this Project Agreement (the “PA”) under the terms and conditions of the Agreement.
- C. Client and COMPANY hereby agree to be bound by the terms of the Agreement with respect to the provision of services under this PA.]

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**2. Interpretation and Construction**

(a) The Parties confirm that the Agreement shall govern the relationship between the Parties. Unless otherwise specifically set forth herein, in the event of a conflict or inconsistency between the terms and conditions set forth in the Agreement and the terms and conditions set forth in this PA, the terms and conditions set forth in the Agreement shall take precedence, govern and control.

(b) The Parties hereby acknowledge that the terms set forth in the Agreement are incorporated herein by reference, as if fully set forth at length therein.

**2. The Services**

A detailed description of the services (the “Services”) is set forth on Exhibit A attached hereto.

**3. Fees**

Set forth on Exhibit B attached hereto is a summary of the costs and fees to be paid by Client to inVentiv for the performance of the Services.

WHEREFORE, the Parties hereto have caused this Project Agreement to be executed by their duly authorized representatives.

**OMEROS CORPORATION**

**VENTIV COMMERCIAL SERVICES, LLC  
[or alternately COMPANY]**

By: \_\_\_\_\_

By: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

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**EXHIBIT A  
THE SERVICES**

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**EXHIBIT B  
FEES AND COSTS**

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**ANNEX B**  
**IDENTIFIED COMPETITORS**

As of May 6, 2014:

[†]

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**PROJECT AGREEMENT  
(DETAILING AND SALES OPERATION SERVICES)**

This Project Agreement (this “Agreement”) is made as of May 12, 2014 (the “Effective Date”) by and between Ventiv Commercial Services, LLC with an office located at 500 Atrium Drive, Somerset, NJ 08873 (“inVentiv”) and Omeros Corporation, with an office located at 201 Elliott Avenue West, Seattle, WA 98119 (“Client”). Client and inVentiv may each be referred to herein as a “Party” and collectively, the “Parties”.

**RECITALS**

A. Client and inVentiv have entered into a Master Service Agreement dated as of May 12, 2014 (the “MSA”).

B. Client and inVentiv desire to enter into this Project Agreement (the “PA” or “Project Agreement”) pursuant to which inVentiv shall provide a field force of inVentiv sales representatives to provide detailing services and shall provide sales operation services as set forth more fully in Exhibits A and B attached hereto.

**1. Interpretation and Construction**

The Parties confirm that the MSA shall govern the relationship between the Parties, and this Project Agreement shall be subject to the terms of the MSA. Unless otherwise expressly set forth herein, in the event of a conflict or inconsistency between the terms and conditions set forth in the MSA and the terms and conditions set forth in this PA, the terms and conditions set forth in the MSA shall take precedence, govern and control. Unless otherwise expressly provided herein (including in any exhibits), capitalized terms used in this Project Agreement have the meanings set forth in the Master Service Agreement.

**2. The Services**

A description of the detailing services (the “Detailing Services”) is set forth on Exhibit A attached hereto and made a part hereof. A description of sales operations, implementation and on-going services is set forth on Exhibit B attached hereto and made a part hereof (the “Sales Operations Services” and, collectively with the Detailing Services, the “Services”).

**3. The Term**

This Project Agreement shall be in effect as of the Effective Date and shall remain in effect until the second (2<sup>nd</sup>) anniversary of the Deployment Date (as defined in Exhibit A) (the time from the Effective Date through such second anniversary, the “Initial Term”), unless extended as provided herein. The period from the Deployment Date until the day prior to the one (1) year anniversary of the Deployment Date shall be referred to herein as “Year One” and the period from the one (1) year anniversary of the Deployment Date through the day prior to the

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two (2) year anniversary of the Deployment Date shall be referred to herein as “Year Two”. The term of this Project Agreement may be extended for additional periods of one (1) year (each an “Additional Term”) upon the mutual written agreement of the Parties not less than ninety (90) days before the end of the Initial Term or any Additional Term (the Initial Term plus any Additional Term(s) collectively, the “Term”).

#### **4. Termination**

(a) Subject to Section 4(b) below, either Party may terminate this Project Agreement in accordance with Section 12 of the MSA.

(b) Notwithstanding Section 12(a)(v) of the MSA, Client may terminate this Project Agreement in its sole discretion only by providing the other Party with at least ninety (90) days’ prior written notice; provided, however, that the actual termination date may not occur prior to the eighteen (18) month anniversary of the Deployment Date.

(c) Client may terminate this Project Agreement upon thirty (30) days’ prior written notice if any of the following events take place: (i) the Product is withdrawn from the market for any reason, or any competent regulatory agency acts to prevent or materially restrict the sale of the Product, such as by governmental seizure or restraining order; (ii) the Product is not approved by the FDA by the Product’s PDUFA date of May 30, 2014; or (iii) the Product is determined to be [†], such [†] or the [†]; provided, however, that if Client terminates this Project Agreement in accordance with this Section 4(b), then Client shall pay inVentiv for the actual cost of all reasonable non-cancellable expenses incurred by inVentiv up to the termination date.

(d) Client may terminate this Project Agreement upon thirty (30) days’ prior written notice if inVentiv fails to reach the milestones and/or deliver the deliverables specified in the Project Plan by the scheduled Deployment Date and such failure is not cured within the notice period, provided, however, that any such failure shall be excused for the duration and to the extent that such failure was caused by Client’s delay in performing its obligations under this Project Agreement.

(e) Client may terminate this Project Agreement upon thirty (30) days’ prior written notice if the inVentiv Sales Representatives fail to achieve the performance standards to be mutually agreed by the Parties within six (6) months following the Deployment Date (such standards, as may be amended from time to time by written agreement of the Parties, “Detailing Services Performance Standards”) and such failure is not cured within the notice -period.

(f) In the case of termination of this Project Agreement by Client (except for termination by Client pursuant to Section 12(a) (ii),(iii) or (iv) of the MSA), or at the end of the Term (or any Additional Term) or in the event Client conducts a Selective Conversion or Block Conversion (as set forth in Section 5 below), Client shall (in addition to all other payment obligations under this Agreement accrued by the effective date of such termination or Conversion) (A) promptly pay (or if paid by inVentiv, promptly reimburse) inVentiv for the amount due any lessor or rental agent of the equipment (e.g. laptop computers, iPads, fleet

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automobiles) (collectively, the “Equipment”) leased or owned by inVentiv and provided to the relevant members of the Project Team (i.e., in the event of termination, all members of the Project Team or in the event of a Conversion, the inVentiv Sales Representative(s) so Converted), for any early termination of the lease or rental agreement for the applicable Equipment, (B) in the event such Equipment is owned by inVentiv, transfer such Equipment to Client and pay an amount equal to the net book value (if any) of such Equipment on the books of inVentiv at the time of the transfer event, or in the event such Equipment is subject to a lease or finance lease, such Equipment may be transferred to Client (subject to the last sentence of this Section 4 (f)) and Client shall assume the responsibility for all further payments due (including costs associated with the transfer), or (C) pay inVentiv the net loss to inVentiv (or, in the case of a net gain to inVentiv, inVentiv shall pay Client the net gain) on such Equipment determined by the difference between the net book value of such Equipment and the actual net price received by inVentiv for the disposal of such Equipment, plus any amounts due by inVentiv in connection with the lease or rental termination and costs associated with the storage and disposal of such Equipment. For clarity, with regards to leased fleet automobiles, all realized and unrealized gains or losses will be combined to determine such net gain or loss. Any proposed transfer of Equipment to Client shall be subject to Client establishing its own relationship and credit with the entity that inVentiv contracted with to lease or rent such Equipment.

#### **5. Conversion (Selective Hiring and Block Conversion)**

(a) Notwithstanding Section 7 of the MSA, during the Term and after the Deployment Date, Client may solicit, employ or retain one or more inVentiv Sales Representatives performing Services hereunder (a “Selective Hiring”). Client shall give forty-five (45) days’ prior written notice to inVentiv of any Selective Hiring. Should there be Selective Hiring by Client, inVentiv will backfill the respective position so as to maintain the previously agreed upon number of inVentiv Sales Representatives performing Services hereunder. In the event Client wishes to implement a Selective Hiring during the Term, Client shall pay inVentiv [†] as a recruitment fee for each replacement/backfill inVentiv Sales Representative.

(b) Notwithstanding Section 7 of the MSA, Client may solicit, employ or retain one or more inVentiv Sales Representatives performing Services hereunder and inVentiv shall not backfill the respective position (a “Block Conversion”) provided that: (i) such hiring may not occur prior to the eighteen (18) month anniversary of the Deployment Date (as defined in Exhibit A) and (ii) Client provides at least forty-five (45) days’ prior written notice to inVentiv of any Block Conversion. In the event Client wishes to implement a Block Conversion, Client shall pay inVentiv a Conversion fee based upon the date of the actual Block Conversion, in accordance with the following table, and in lieu of any payment under Section 7(c) of the MSA:

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	<b>From the Deployment Date through the 18 month anniversary of the Deployment Date</b>	<b>From the day after the 18 Month anniversary of the Deployment Date until the end of Year Two</b>	<b>After Year Two</b>
<b>Conversion Fee per inVentiv Sales Representative for Block Conversion</b>	No conversion permitted	[†]	[†]

(c) Client understands and agrees that inVentiv cannot guaranty that any inVentiv Sales Representative will agree to participate in a Selective Hiring or Block Conversion. In the event a Sales Representative does not agree to participate in a Selective Hiring or Block Conversion, Client will have no payment obligation to inVentiv under this Section 5 with respect to such Sales Representative.

(d) In the event Client implements a Selective Hiring or Block Conversion, the Parties agree that any inVentiv proprietary training materials made available to the inVentiv Sales Representatives will be immediately returned to inVentiv, it being understood and agreed that the inVentiv proprietary training modules constitutes valuable and proprietary information of inVentiv and is subject to the confidentiality obligations set forth in Section 6 of the MSA. For clarity, such inVentiv proprietary training materials excludes any materials provided by Client, any Product-specific materials, or other materials created for Client or Client’s Product by inVentiv in the course of performing services under this Project Agreement or any other Project Agreement under the MSA. Within fifteen (15) days of implementing a Selective Hiring or Block Conversion, Client shall use commercially reasonable efforts to return to inVentiv any originals and copies of such inVentiv proprietary training modules which had been in possession of the converted inVentiv Sales Representatives.

(e) In the event Client conducts a Selective Hiring or Block Conversion (collectively, a “Conversion”) and the converted inVentiv Sales Representative had been provided with use of a fleet automobile leased, rented or owned by inVentiv and Client wishes to commence an arrangement with the fleet vendor to assume such cars (and all associated costs and liabilities) under Client’s name, the converted inVentiv Sales Representative may only to continue to have access to such automobile following the Conversion if Client either: (i) registers the fleet automobile under its name; or (ii) ensures that inVentiv remains named as an additional insured under Client's automobile insurance policies until such time as the vehicle is registered in Client’s name (which shall occur no later than three (3) months following the Conversion). The Parties understand and agree that it is solely Client’s obligation to ensure one of the above actions are taken and Client shall be responsible for indemnifying, defending and holding inVentiv harmless for all damages resulting from Client’s failure to take such action. The Parties further agree that on the effective date of the Conversion, Client shall destroy the inVentiv insurance card(s) in the fleet vehicle(s) of the converted inVentiv Sales Representative.

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**6. Return of Client Materials**

Except as set forth in Section 5, if any inVentiv Sales Representative leaves the employ of inVentiv or ceases to perform Services (including in connection with the expiration or termination of this Project Agreement), inVentiv shall use commercially reasonable efforts to retrieve from such person all materials provided by Client, any Product-specific materials, or other materials created for Client or Client's Product by inVentiv in the course of performing Services under this Project Agreement (or any other Project Agreement under the MSA), and shall provide such materials to the replacement inVentiv Sales Representative, or, if there is no such replacement (including in the case of expiration or termination of this Project Agreement), return the materials to Client within fifteen (15) business days.

**7. Fees**

Set forth on Exhibit C are the costs and fees to be paid by Client to inVentiv for the performance of the Services.

**WHEREFORE**, the parties hereto have caused this PA to be executed by their duly authorized representatives on the day and year first above written.

**OMEROS CORPORATION**

By: /s/ Gregory A. Demopoulos

Name: Gregory A. Demopoulos, M.D.

Title: Chairman & CEO

Date: 5/13/14

**VENTIV COMMERCIAL SERVICES, LLC**

By: /s/ Theodore Wong

Name: Theodore Wong

Title: VP & CFO

Date: 5/13/14

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**EXHIBIT A**  
**THE DETAILING SERVICES**

inVentiv will provide Client with a field force that shall consist of twenty (20) full-time sales representatives (the “inVentiv Sales Representatives” or “Sales Representatives”) who shall detail Client’s Product by making Calls pursuant to a Call Plan on Targets. The inVentiv Sales Representatives shall be managed by one (1) shared National Business Director (“NBD”) and one (1) shared Operations Manager (“OM”) each of whom shall also be inVentiv employees. The inVentiv Sales Representatives, the NBD and the OM may be collectively referred to herein as the “Project Team”.

In the event that the Parties desire to increase the type and / or number of Project Team members providing Services under this Project Agreement they may do so by utilizing a Project Team Member Request Form (the “Request Form”) in a format that is substantially similar to the one attached hereto as Exhibit A – 1. The details set forth in the Request Form shall be mutually agreed upon by the Parties. For clarification, the Request Form may not be used in those situations where it is the intent of the Parties to amend terms and conditions of this Project Agreement other than those specific items set forth on the Request Form.

In connection with the promotion of Client’s Product, inVentiv shall provide the Client with following Detailing Services.

**I. ADDITIONAL DEFINED TERMS**

(a) “Adverse Event” means the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to the Product, whether or not considered causally related to the Product, the exacerbation of any pre-existing condition(s) occurring during the use of the Product, or any other adverse experience or adverse drug experience described in the FDA’s Investigational New Drug safety reporting and New Drug Application postmarketing reporting regulations, 21 C.F.R. 312.32 and 314.80, respectively, as they may be amended from time to time. For purposes of this Project Agreement, “undesirable medical condition” shall include symptoms (e.g., nausea, chest pain), signs (e.g., tachycardia, enlarged liver) or the abnormal results of an investigation (e.g., laboratory findings, electrocardiogram), including unfavorable side effects, toxicity, injury, overdose, sensitivity reactions or failure of the Product to exhibit its expected pharmacologic/biologic effect.

(b) “Call” means the activity undertaken by an inVentiv Sales Representative to detail the Product, further described as a face-to-face presentation by an inVentiv Sales Representative to a Target and will include providing the Target with Product Literature as directed by Client.

(c) “Call Plan” means a plan designed by Client, which is intended to enhance the efficiency and effectiveness of the inVentiv Sales Representatives in making Calls. The Call Plan will be maintained by inVentiv at its offices with a copy of such Call Plan maintained by client at its offices, and may be amended or reconfigured once per calendar quarter by Client.

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(d) “Deployment Date” means the date of the first Call which is anticipated by the Parties to be on or about August 4, 2014. The actual Deployment Date will take precedence over the date specified herein.

(e) “inVentiv Sales Representative” or “Sales Representative” means an individual employed by (or, if applicable, an independent contractor to) inVentiv who is engaged under this Project Agreement to detail the Products.

(f) “Minimum Detailing Standards” means the minimum standards for detailing by an individual Sales Representative under this Project Agreement, such standards to be decided upon by the Parties within six (6) months following the Deployment Date.

(g) “Product” shall mean Omidria (phenylephrine-ketorolac ophthalmic injection) 1%/0.25% or other Client products added to this Project Agreement with the mutual written consent of the Parties.

(h) “Product Literature” shall mean promotional, informative and other written information concerning the Product. All Product Literature shall be prepared and provided by Client.

(i) “Product Quality Complaint” means any and all manufacturing or packaging-related complaints related to the Product, including (a) any complaint involving the possible failure of the Product to meet any of the specifications for the Product; (b) any dissatisfaction with the design, package or labeling of the Product; or (c) any Adverse Event that may involve the quality of the Product, including lack of effect, infection or request for testing.

(j) “Targets” mean the licensed practitioners who are identified by Client as potential prescription writers and/or customers for the Product as provided by Client to inVentiv.

## **II. HIRE STATUS AND TRAINING; EXCLUSIVITY**

(a) inVentiv will recruit and hire the full-time inVentiv Sales Representatives and assign the necessary the shared resources to Client’s project. A complete description of the sourcing, screening and recruiting services is attached hereto as Exhibit A-2. The Client shall notify inVentiv in writing of the date on which inVentiv may commence such hiring, such date to be selected in Client’s sole discretion (the “Hiring Start Date”) For clarity, inVentiv shall not hire any member of the Project Team until the Hiring Start Date.

inVentiv shall provide the inVentiv Sales Representatives with salary, benefits, fleet automobiles (e.g. Chevrolet Malibu, Chevrolet Equinox (snow belt territories) or similar model), iPads, laptop computers, sales force automation software, printers and bonus as agreed by the Client and as set forth in Exhibit C, Section II, Pass-Through Costs. inVentiv shall provide the NBD and OM with salary, benefits, iPads, laptop computers, sales force automation software and printers as needed to perform their respective duties under this Project Agreement.

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(b) Training - The training responsibilities of the Parties are as follows:

(i) inVentiv shall be responsible for training members of the Project Team concerning: selling skills, inVentiv human resource policies, procedures and administration and other applicable inVentiv internal human resource and general compliance policies and procedures, prior to the Deployment Date (or, in the case of inVentiv Sales Representatives hired after the Deployment Date, prior to their deployment).

(ii) Client shall be responsible for training members of the Project Team concerning all Product specific information including Product Quality Complaint handling procedures, applicable specific Client health care compliance policies and Client customer service policies and procedures, orientation to Client's business, compliance with Applicable Law, and Adverse Event reporting policies and procedures, prior to the Deployment Date (or, in the case of inVentiv Sales Representatives hired after the Deployment Date, prior to their deployment).

(iii) The Parties agree to work together to mutually determine if, when, and at what cost additional training shall be provided to members of the Project Team, provided that, at Client's request and expense, inVentiv will perform any follow-up or refresher training on a schedule to be mutually agreed upon by the Parties.

(vi) inVentiv shall maintain during the Term and for a period of three (3) years thereafter, records of any training it conducts under this Project Agreement.

(c) Exclusivity. The inVentiv Sales Representatives shall be solely and exclusively used for the Detailing Services as set forth herein, and shall not, during the Term, market, promote or sell any pharmaceutical product other than the Product. In addition, during the Term, the National Business Director and Operations Manager shall not participate in (including through the coordination or supervision of other teams of sales representatives) the marketing, promotion or selling of any product for an Identified Competitor. Upon any breach of this Section II(c), Client may, in addition to any other rights or remedies to which Client may be entitled in law or equity, terminate this Project Agreement by providing thirty (30) days' written notice of termination to inVentiv specifying such breach, provided that the termination shall not become effective if inVentiv cures such breach within such thirty-day period.

### III. PERFORMANCE

If Client believes in good faith that the performance of any inVentiv Sales Representative is unsatisfactory or is not in compliance with the provisions of this Agreement, Client shall notify inVentiv and inVentiv shall promptly address the performance or conduct of such person in accordance with its internal human resource policies. In the event that Client determines in good faith that an inVentiv Sales Representative has violated any Applicable Law or policy, Client shall notify inVentiv (in writing). inVentiv shall promptly address the issue and take all reasonable and appropriate action (including but not limited to termination of such employee) consistent with inVentiv's internal human resource policies and procedures, which in the case of

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any failure to meet the Minimum Detailing Standards or for any violation of Applicable Law or policy, shall include at a minimum reassigning such inVentiv Sales Representative so that such person no longer performs Detailing Services or any other services for Client.

#### **IV. CALLS AND TARGETS**

The inVentiv Sales Representatives shall provide information to the Target about the Product when making Calls as directed by Client. Client is solely responsible for the content, production and distribution (to the inVentiv Sales representatives) of the Product Literature, and the inVentiv Sales Representatives shall utilize only such Product Literature when making Calls. Each inVentiv Sales Representative shall record information concerning each Call and concerning the profile of each individual Target (or other physician called upon) on whom the inVentiv Sales Representative calls. To the extent not prohibited by any third-party agreement, and subject to the Parties' obtaining any necessary licenses or rights from third-parties, Client shall permit inVentiv to access and use all Target, sales and Call-related data that supports or is associated with the Services that are performed in accordance with this Agreement (the "Data"). The Data shall be used by inVentiv for the purpose of evaluating the performance of its Project Team members and, provided that inVentiv de-identifies all Client and Product specific components of the Data, for business development and analytics purposes, provided, however, that inVentiv shall not use any such Data in connection with any such activities associated with or directed at any third party without the prior written consent of Client.

For the avoidance of doubt, all such Data, as well as any data stored on behalf of the Client by inVentiv in accordance with this Project Agreement, shall, as between the Parties, be owned solely and exclusively by Client.

To the extent permitted by applicable law, Client shall be permitted to coach Sales Representatives on effective selling strategies for the Products, evaluate and recommend actions to improve the Call Plan to conform to Minimum Detailing Standards, participate in "ride alongs" with Sales Representatives when making Calls, and train Sales Representatives about the Products and requisite medical background information.

#### **V. REQUESTS FOR MEDICAL INFORMATION; REGULATORY REPORTING**

##### **(a) Requests for Medical Information.**

(i) Client shall have the exclusive right to respond to all questions or requests for information made to inVentiv or its Sales Representatives by any medical professionals or any other person or entity about the Product, if such questions or requests (i) warrant a response beyond the understanding or knowledge of the Sales Representative or (ii) are beyond the scope of the Product labels and inserts or Product Literature (a "Medical Information Request").

(ii) inVentiv shall promptly communicate to Client, or any third-party vendor designated by Client to process such information, all Medical Information Requests received by inVentiv or the inVentiv Sales Representatives. If Client designates such a third-party vendor or

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changes such third-party vendor (which Client may do from time to time in its sole discretion), it shall notify inVentiv in writing of the name and contact information for such new vendor.

(b) Regulatory Reporting.

(i) Client shall be solely responsible for making all reports, submissions and responses to Agencies concerning the Product, including reporting Adverse Events and Field Alerts, as required by Applicable Law. In addition, Client shall be solely responsible for (A) taking all actions and conducting all communication with all third parties with respect to all Product Quality Complaints, including complaints related to tampering or contamination, and (B) investigating all Product Quality Complaints, Adverse Events, and Field Alerts with respect to the Product. inVentiv shall, at Client's expense, cooperate with all of Client's reasonable requests and use its diligent efforts to assist Client in connection with (x) preparing any and all such reports for any relevant governmental or regulatory authority, (y) preparing and disseminating all such communications to third parties, and (z) investigating and responding to any Product Quality Complaint or Adverse Event.

(ii) inVentiv shall provide notice to Client within two (2) business days from the time it becomes aware of an Adverse Event associated with the use of the Product (whether or not the reported effect is (A) described in the full prescribing information or the published literature with respect to the Product or (B) determined to be attributable to the Product) or any information in or coming into its possession or control concerning such Adverse Event by providing notice to Client or any third-party vendor designated by Client to process such information. If Client designates such a third-party vendor or changes such third-party vendor (which Client may do from time to time in its sole discretion), it will notify inVentiv in writing of the name and contact information for such new vendor.

(iii) inVentiv shall provide notice to Client within two (2) business days of the time it becomes aware of (A) any information that might necessitate the filing by Client of a field alert report, as required under 21 C.F.R. § 314.81(b)(1) (a "Field Alert"), as such regulation may be amended from time to time or (B) any Product Quality Complaint associated with use of the Product, in each case ((A) or (B)), by providing notice to Client or any third-party vendor designated by Client to process such information. If Client designates such a third-party vendor or changes such third-party vendor (which Client may do from time to time in its sole discretion), it will notify inVentiv in writing of the name and contact information for such new vendor.

(iv) inVentiv shall put in place procedures and protocols that shall be actively monitored by inVentiv to ensure that all relevant information regarding the matters referred to in this Section V that come to the attention of any member of the Project Team is promptly conveyed to Client so that Client can comply with applicable reporting requirements. As to any Adverse Event of which the Project Team is made aware, inVentiv and the Project Team shall not make any statement or give any opinion (written or verbal) to any person or entity that could reasonably be construed as an admission of fault on Client's part or a promise that Client will compensate any person or entity with respect thereto.

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## VI. THE PRODUCT(S)

(a) The Product shall be promoted by inVentiv under trademarks owned by or licensed to Client and are Products which Client has all lawful authority necessary to market and sell the Products in all geographic areas where the Products are to be promoted under this PA. This Agreement does not constitute a grant to inVentiv of any property right or interest in the Products or the trademarks owned by or licensed to Client. inVentiv recognizes the validity of and the title of Client to all its owned or licensed trademarks, trade names and trade dress in any country in connection with the Products, whether registered or not. Client represents to inVentiv that to its knowledge, neither those trademarks, trade names and trade dress nor the promotion of the Products by inVentiv infringes on any intellectual property right of any other person or entity.

(b) Client shall have the sole right and responsibility of establishing or modifying the terms and conditions of sale of Products. Client shall be exclusively responsible for accepting and filling purchase orders, billing, and returns with respect to the Product. If inVentiv or any inVentiv Sales Representative receives an order or a request to order a Product, it shall, within one (1) business days, forward such order or request to Client for acceptance or rejection, which acceptance or rejection shall be at Client's sole discretion.

## VII. HIRING PROFILE

In selecting Sales Representatives, inVentiv shall use the preferred hiring profile approved by Client as set forth below and shall provide the sourcing, screening and recruiting services identified in Exhibit A-2. inVentiv shall use diligent efforts to hire Sales Representatives in accordance with the preferred hiring profile and to confirm the accuracy of information concerning background and experience received from applicants for positions of Sales Representatives. inVentiv shall not knowingly employ or otherwise retain, or permit to be retained as a Sales Representative, a practicing physician or a person affiliated on a professional level with or employed by any physician, physician practice or other healthcare professional or provider or a person who is in a position to unduly influence the purchase of the Products or whose employment or retention for this purpose is otherwise prohibited by Applicable Law.

### Qualifiers

Must have:

- 4 year college degree
- Outside sales experience
- Dedication to full time employment (no employment or income-producing activities outside of inVentiv)
- Clearance on all pre-employment screening
- Ability to attend required training programs
- Ability to participate in minimal overnight travel

### Business Experience Preferences

Most preferable to least preferable:

[†] experience

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[†] experience  
[†] experience  
[†]  
[†] experience

#### Professional Skills

Desired:

Professional image and conduct  
Intelligence  
Analytical/business oriented  
Persuasive  
Organized and high planning aptitude  
Goal/objective oriented  
High degree of personal motivation and drive  
Honest  
Oral & written communication skills.

### **VIII. BACKGROUND CHECKS**

inVentiv shall be responsible for performing drug testing and background checks of all Sales Representatives. inVentiv represents and warrants that it will complete or cause to be completed a thorough background check of all Sales Representatives. This will include the following: criminal check, Social Security check, drug screen, motor vehicle record check, education check, and past employer check. inVentiv further represents and warrants that it will perform or cause to be performed background checks to confirm that no Sales Representative:

- (a) is an excluded person on the Office of Inspector General's List of Excluded Individuals/Entities and is not on the General Services Administration Excluded Parties List (as of the date the background check is performed);
- (b) is, so far as it is aware, an unfit or an improper individual for the performance of the Services;
- (c) is, so far as it is aware, engaged in any fraudulent or unlawful activity, or other inappropriate conduct as measured by the other requirements of this Agreement.

inVentiv further covenants to provide prompt written notice to Client in the event it becomes aware that any Sales Representative falls within any of the categories set forth in this Section VIII(a)-(c). inVentiv shall institute prompt corrective or disciplinary action against any Sales Representative who fails to meet the requirements set forth in this Exhibit A. inVentiv further agrees to cooperate and comply with all investigations by or on behalf of Client with respect to wrongdoing, or alleged or suspected wrongdoing, in respect of any obligations of inVentiv or any Sales Representative under this Agreement.

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## IX. REPRESENTATIONS AND UNDERTAKINGS

(a) inVentiv represents, warrants and covenants that:

(i) it, as well as the inVentiv Sales Representatives, shall perform the implementation of Client's detailing program in a professional manner consistent with industry standards and with that level of care and skill ordinarily exercised by other competent professional contract service organizations in similar circumstances and in accordance with this PA, the MSA, and those specifications and timelines which inVentiv and Client agree to (in writing) and which are not otherwise set forth herein or in the MSA. inVentiv shall ensure that its employees or agents complete the Services (including those in Exhibit B) in a timely manner and in accordance with the terms of this PA;

(ii) the inVentiv Sales Representatives shall make only those statements and claims regarding the Product, including as to safety and efficacy, that are consistent with the labeling of the Product, the inserts for the Product, and the Product Literature, and shall not add, delete or modify claims of efficacy or safety of the Products, nor make any changes (including but not limited to, underlining or otherwise highlighting any language or adding any notes thereto) in the Product Literature. inVentiv shall, and shall permit the inVentiv Sales Representatives to, use only the Product Literature provided by Client. inVentiv and the inVentiv Sales Representatives shall not develop, create, or use any other promotional material or literature or alter Product Literature provided by Client. inVentiv shall immediately cease the use of any Product Literature when instructed to do so (in writing) by Client. inVentiv shall use the Product Literature only for the purposes of this Agreement;

(iii) it shall not, and shall ensure that all Sales Representatives shall not, directly or indirectly, pay, offer or authorize payment of anything of value (either in the form of compensation, gift, contribution or otherwise) to any person or entity in a position to order or purchase the Products contrary to any law;

(iv) it shall not, and shall ensure that all Sales Representatives shall not, directly or indirectly, make any representations or warranties relating to the Products that conflict, or are inconsistent with the Food and Drug Administration approved labeling for the Products, and shall not make any untrue or misleading statements or comments about the Products, Client, any employees of Client, any competitors of Client, or other products;

(v) it shall ensure that each Sales Representative shall promote, market and sell the Products in accordance with Applicable Law; and

(vi) it shall ensure that any Data used by or on behalf of inVentiv in accordance with Section IV of this Exhibit A is properly de-identified before such use and such use is otherwise in compliance with Applicable Law.

(b) Client represents, warrants and covenants that:

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- (i) it recognizes that for inVentiv to comply with its obligations hereunder, it shall need the good faith cooperation of Client to provide inVentiv with the necessary materials and assistance required to enable inVentiv to perform the Services;
- (ii) it will comply with Applicable Law in its marketing, promotion and sale of the Products (leaving aside any acts or omissions of inVentiv or the inVentiv Sales Representatives with respect thereto);
- (iii) it shall ensure that none of its employees add, delete or modify claims of efficacy or safety of the Products, nor makes any changes (including but not limited to, underlining or otherwise highlighting any language or adding any notes thereto) in the Product Literature during the training on the Products or during any communications with inVentiv employees, provided, however, that in no event shall Client be prohibited from making changes to the Product Literature that Client believes are necessary or appropriate and in compliance with Applicable Law;
- (iv) it shall ensure that none of its employees working with the Project Team or in connection with the Services, directly or indirectly instruct any inVentiv employee to pay, offer or authorize payment of anything of substantial value (either in the form of compensation, gift, contribution or otherwise) to any person or entity in a position to order, recommend or purchase the Products contrary to any law; and
- (v) neither it nor any of its employees directly or indirectly instruct any inVentiv employee to make any representations or warranties relating to the Products that conflict, or are inconsistent with Applicable Law or the Food and Drug Administration approved labeling for the Products.

(vi) Client shall:

- A. provide inVentiv Sales Representatives with all Product Literature.
- B. inform inVentiv promptly of any changes in the Product Literature or in information concerning the Products which Client believes are necessary or appropriate in order to be in compliance with all Applicable Law.
- C. as permitted under Applicable Law, respond appropriately and in a timely manner to any inquiry concerning a Product communicated to inVentiv from any licensed practitioner and communicated by inVentiv to Client.

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**EXHIBIT A-1**

**PROJECT TEAM MEMBER REQUEST FORM**

This Request for Additional Project Team members is issued pursuant to the Master Services Agreement between Ventiv Commercial Services, LLC (“inVentiv”) and (“Client”) dated \_\_\_\_ and the Project Agreement issued thereunder dated \_\_\_\_\_.

<b>PART 1</b>	<b>To be completed by Client Attach any relevant, helpful information</b>
NUMBER AND TYPE OF PROJECT TEAM PERSONNEL REQUESTED	
TERRITORY LOCATION(S)	
REQUESTED HIRE DATE	
DEPLOYMENT DATE	
AUTHORIZED CLIENT REPRESENTATIVE SUBMITTING REQUEST	Signature: _____ Name: Title: Date: Phone: Fax:
<b>PART 2</b>	<b>To Be Completed by inVentiv</b>
NEW PROJECT TEAM MEMBER DETAILS (the fees set forth below are per Project Team member added):  Implementation Fee \$ _____ Added Fixed Monthly Fee: \$ _____ Target Start Date: _____	Request is Accepted, and Recruitment shall begin immediately upon Client approval of New Representative Details:  _____ (sign and date) inVentiv Contact Person: Phone:
	<b>New Project Team member accepted and customer understands that recruiting will begin immediately:</b>  (sign and date) Client Contact Person: Phone:

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**EXHIBIT A-2**  
**SOURCING, SCREENING AND RECRUITING SERVICES**

<b>Service Type</b>	<b>To be done?</b>	<b>Description</b>
Requisition – ATS Management	Yes	Managing the requisition process from initiation through approval and proper storage and handling of open and closed requisitions.
ATS – Career Bridge Web Site	Yes	Establish an inVentiv firewalled Applicant Database and Link that connects and brands all Client opportunities. All candidate data is then transferred and owned by Client at end of project.
Manager Communication and Guidance – Custom Recruiting Kick Off Process.	Yes	Work directly with hiring manager from “kick off” through requisition closing and handle all recruiting communications and process guidance including candidate feedback.
Sourcing and Database Mining	Yes	Establish sourcing campaign based on requirements and position to include academic, diversity, database mining, social networking, electronic recruiting and direct recruiting campaigns. Includes inVentiv standard resources only and any client required resources would be a pass through to CLIENT.
Employment Branding	No	Develop employment marketing pieces to include Employment Value Proposition and basic job branding templates.
Manage Internal Client Candidates	No	Upon CLIENT identification and candidate approval, inVentiv will screen and manage communications in alignment with CLIENT process to be considered for open positions.
Establish Customized Screening & Assessment Process	Yes	Develop and train recruiting team to deliver a customized screening process through phone screen and behavioral phone interviews. This will be developed in conjunction with CLIENT.
Resume and Online Screening	Yes	Review all candidates per requisition that have applied or have been added to the requisition. Ensure they meet the minimum established qualifications via resume and online screening questions and move them to a “qualified” stage in ATS requisition.
Initial – Functional Phone Screen	Yes	1st level “basic” screening of candidates via phone to ensure present organization, availability and interest as well as review minimum qualifications and assess communication.
In-Depth Behavioral Based Phone / Video Interview and Summary	Yes	In-depth interview with candidates including behavioral interview, skills assessment, and other criteria as defined. This includes summary write up and documentation in ATS. No Video
3 <sup>rd</sup> Party Assessment Program	No	Manage the administration and coordination of issuing any online or related assessment technology to potential candidates. This does not include technology development and implementation. Cost of purchase of this program would be a pass through.
Interview Coordination	Yes	Schedule candidate and manager in-person or phone interviews including meeting rooms, travel and tracking of expenses. Onsite staff will be pass through.
Candidate Care Program	Yes	Manage candidate communications with those candidates deselected from the process. This includes electronic notification from system as well as letters to those who were engaged.
Reference Checks	Yes	Conduct reference checks on finalist candidates pre-offer.

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Data and Metrics Tracking	Yes	Develop and track all front end recruiting metrics as established with CLIENT.
Staffing Vendor Management	Yes	Establish, negotiate and manage staffing vendor program including selection, oversight and contract development.
Candidate Data/File Collection and Transfer	Yes	InVentiv will work closely with CLIENT HR/RPO to provide required data and information captured during the front end of recruiting process for input into ATS. Including candidate application process, data points, hiring/interviewing event files etc. To be provided to CLIENT through desired format but input by CLIENT/RPO.
Referral Program Management	Yes	Develop tracking of referrals and screen, interview and process all referrals. Program development and payout not included.
Offer Letter Generation	Yes	Develop and initiate offer letters upon CLIENT approval and track and file executed files.
Pre Employment Management	Yes	Conduct, process and manage all pre-employment screening and track documents and issues.
Candidate Satisfaction Survey	No	Initial or annual survey to determine feedback and quality of service being offered to candidate

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**EXHIBIT B**  
**THE SALES OPERATIONS SERVICES**

**1.0 Executive Summary**

This Exhibit B describes the work required for the initial implementation and ongoing operation of the Sales Operations Services to support the Project Team, which will initially include twenty (20) inVentiv Sales Representatives. Any changes to the assumptions, deliverables, or scope of work described in this document or any new work requests will follow Section 4.0, Change Control Process, of this document.

**2.0 Scope of Services**

**2.1 Generally**

This Exhibit B defines the work related to the following service areas for the initial implementation and ongoing operation of the Sales Operation Services within the following areas:

- Project Management
- Customer Relationship Management (CRM)
- Data Management
- Analytics & Reporting
- Targeting & Call Plan Administration
- Incentive Compensation
- Sales Administration (Fleet, Human Resources and Operations Management)
- Travel and Expense Management
- Field Support Services
- Sales Training Services
- Quality Management and Assurance
- Compliance

**2.2 Diligence**

Without limiting any obligations of inVentiv as set forth herein, inVentiv shall perform all activities assigned to it under the applicable Project Plan and shall use commercially reasonable efforts to perform such activities in accordance with any applicable time periods, milestones and deadlines set forth in such Project Plan.

**3.0 Scope of Work Definition**

**3.1 Project Management**

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inVentiv has developed a project implementation methodology based upon industry best practices into the most efficient process and method for conducting and managing projects.

The inVentiv project team will approach this engagement with the following perspectives in mind:

- Provide a practical approach to project planning, execution and service delivery
- Maintain discipline and structure without constraining the project efforts
- Frame the project within the strategies of the clients business requirements

inVentiv will provide a fully integrated project management approach for the implementation of the Sales Support Services and hereinafter referred to as the “Project”. The Project will be managed by a dedicated project manager (“Project Manager”) who will be responsible for the following:

- Leadership of Project kick-off meeting to include review of scope, timelines, and assumptions for each functional area, project team member introduction, and status reporting formats and meetings.
- Integration of all project activity, timelines, and deliverables across all functional areas into a consolidated project plan (the “Project Plan”).
- Leadership, facilitation, and documentation of all meetings including meeting notes and action items.
- Management of the Project Plan including task management, escalation of issues, risk identification, and interdependencies through project documentation including:
  - o Issue tracker
  - o Milestone tracker
  - o Action item tracker
- Project status meetings & Project status reporting including weekly status report (WSR) dashboards to be provided to Client.
- Project close-out & lessons learned session to include any information that can be applied to the ongoing operational management of the client after the initial deployment is complete.

The Project Manager will be assigned to Client during the implementation period, including the preparation and delivery of the kick-off meeting through the completion of the Project close-out and lessons learned. After the implementation period is over and field users are deployed, the operational support of the client will be provided by the shared Operations Manager with support provided as needed by the Project Manager.

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### 3.2 Customer Relationship Management (“CRM”)

inVentiv will provide a fully functioning CRM application utilizing our proprietary, pre-configured build, referred to as the inVentiv General Development Org or “GDO”, of Veeva CRM software, an industry leader in providing cloud-based CRM applications to the Life Sciences industry. The CRM Services include those supported within the inVentiv Health GDO including:

- **Customer Management** across Account Profiles (Individuals & Organizations)
- **Call Recording**, Reporting, and loading of Call Plans
- **Closed-Loop Marketing (“CLM”)**; loading and presentation of digital media as part of integrated call record
- **Sample management** and recording of samples and physician signature capture as part of integrated call record, including PDMA/CFR Part 11 Validation
- **Medical Inquiry Request Form (“MIRF”)** including physician signature capture
- **Field Coaching** configuration
- Pre-established **Reports & Dashboards** based on industry best practices to enhance field and field management performance (online only)
- **iPad/Online Platform** options including Online/Home Office PC, Field Tablet PC, and iPad to **support mobility needs and improved customer interaction**

The CRM implementation will be led using an Agile development approach including the following deliverables:

Project Deliverable	Definition
Initial Requirements	Demonstration of GDO and discussion of client needs and business environment to support the general usage and end-user experience; will include Accounts, Functions, Call types, Products, Customer Maintenance, etc.
Alpha Review	First iteration of the Client configuration based on requirements gathered in the initial requirements session. Detailed demonstration of the client configuration for more in-depth review of client requirements.
BRD (Business Requirements Document)	After the Alpha review inVentiv Health will provide the client with a draft BRD document which summarizes all end-user system requirements taken from both the initial and alpha requirements sessions. The BRD will form a basis for the final product configuration specifications, Risk Assessment, Testing, Training, and Validation (if applicable).
Beta Review	The final phase of the client requirements will be a Beta review, which will allow for any changes to the system requirements for final testing and production readiness.
BRD Sign-Off	Any changes or additions to the requirements during the Beta review will be incorporated into the final BRD and submitted to the client after the Beta session for final approval and signature.

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The scope of the CRM delivery and associated timelines for the Project assumes the following:

- Necessary Client members are available for the initial, alpha, and beta review meetings (each typically 3 hours), based on the weeks assumed in the project timeline provided in Section 3.0, Implementation Timeline (alpha/beta can be done via WebEx)
- Sign-off of documentation within 5 days of delivery by necessary Client members
- No customization of code outside of Veeva provided configuration capabilities
- Use of standard MIRF functionality and data extracts to Medical Information System, not to include any Adverse Events reporting or recording.
- Linking to company or external web-based systems within Veeva Tab structure
- Sample management functionality and data feeds for sample shipments, SLN validation, and sample product information as determined by client requirements
- Inclusion of sales data within standard Vinsights reporting functionality (online only)
- Field Coaching Report (“FCR”) originates from manager, not representative, including data entry only, form will not be pre-populated with any data from any source
- Call History within Sales Force Automation (“SFA”) system not to exceed 15 months (5 Quarters) without purchasing additional data storage from Salesforce.com
- Ongoing support for CRM system including tier 2/technical support for escalated calls from field support desk, and home office support needs.
- Additional system enhancements requested post-deployment will be managed through the Change Management process in Section 5.0.

### **3.3 Data Management**

inVentiv will provide data loads and data integration services for all needed data imports and exports. Data management services includes data flowing to and from the Veeva CRM application including Client data sources, third parties (i.e. sales data), or service partners. The data management team will work very closely with the CRM and analytics & reporting tools to ensure that all customer business rules and data requirements are properly understood and planned for in the overall implementation plan. This Project assumes typical data loads and ongoing data support as provided below:

A full description of all data files and interfaces will be provided in the Data Requirements Document (“DRD”), which will be included as part of the Project Plan with necessary approvals from Client project leads.

Data interfaces typically include the following:

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Initial data loads using agreed upon inVentiv/Client formats including:

- Territory Hierarchy
- Customer Universe, Alignments, and Targets/Call Plans
- Product Information
- Call History (if required)

Reoccurring data imports at set frequencies and in agreed upon formats for ongoing Customer and Territory management including:

- Prescriber/Account Sales Data
- Prescriber Payer Data
- Call Plan/Targets
- Customer Universe Updates-Validation Responses
- Sample Shipment Files
- Promotional Items

Reoccurring data extracts provided at set frequencies to either home office or third party vendors as needed for processing including:

- Call/Activity data
- Medical Inquiries
- Sample Activity: Shipping Receipts/Lots, Sample Drops, Inventory, etc.
- DME Spend data from Concur
- Customer Universe Validation Requests

Standard Data Management services will be provided for the ongoing maintenance of the systems and data including:

- State license validation process to reduce field impact in sampling (Weekly)
- PDRP flagging on accounts (Monthly)
- Routine merging of addresses (Weekly) and accounts (Quarterly)
- Setup of integration between our Veeva and Data Warehouse which allows roster, territory hierarchy and product management to be seamless
- Time off Territory and Holiday updates
- Ongoing maintenance of Sales and Payer data in the Vinsights area of Veeva which allows report display
- Training database setup and management
- Tier 2/Technical support for data issues routed from the Field Support Desk

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The scope of the Data Management delivery and associated timelines for the project assumes the following:

Project Deliverable	Definition
Initial Requirements	Discussion of client needs regarding data loads, extracts, and imports and finalization of project plan and scope based on SOW assumptions and Change Management process
Third Party Agreements (TPA)	inVentiv Health will secure, in coordination with Client, any rights and licenses that inVentiv needs from external vendors such as Sales Data companies which require TPA for data services to be provided
DRD (Data Requirements Document)	inVentiv Health will provide the client with a DRD document which summarizes all data loads, imports, and extracts, as well as any business rules, frequencies, and formats associated with the data services to be provided as part of implementation and ongoing data management services, the DRD draft will be reviewed, modified as needed, and signed by the client to confirm project deliverables
Test Files	The client or Third Parties will provide needed test files in specified formats and agreed dates in the project plan based on the implementation schedule
Final Production Files	The client or Third Parties will provide final production files in specified formats and agreed dates in the project plan based on the implementation schedule

inVentiv shall maintain all data in the Veeva CRM system relating to the Detailing Services for a minimum of fifteen (15) months, and at Client's request and expense, shall store such data for longer periods.

Promptly upon the expiration or termination of this Project Agreement, inVentiv shall return, or cause to be returned, in a format reasonably acceptable to inVentiv, any data stored in the Veeva CRM system.

### 3.4 Analytics & Reporting

The project assumes general field activity reporting will be provided in the Veeva CRM Reporting environment utilizing inVentiv's pre-configured reporting tools to optimize field performance and implementation setup time. inVentiv will configure the template reporting tools to include client specific fields and terminology where applicable within Veeva and Salesforce.com guidelines.

After initial implementation, configuration and approval of alpha/beta reviews, inVentiv will provide documents, in the form of Business Requirements Documentation

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(“BRD”) and Reporting Requirements Document (“RRD”). These documents will be signed by both Client and inVentiv to ensure coordination and agreement on the overall requirements. Any additional dashboards will be assessed and scoped based on Client needs following the specified Change Management process implemented by inVentiv.

Veeva reporting can be implemented for the following:

- Field Activity: All Levels (Territory /District/Region/Home Office), See Table (Veeva Field Force Reporting Tools) for details including the following:
  - Call Activity
  - Call Plan Adherence
  - Sample Activity
  - CLM Utilization
  - Synchronization Monitoring
  - Manager Exceptions & Administration
  - Veeva Field Force Reporting Tools

The Veeva template field reporting package is designed to drive sales behavior in the following ways:

- Evaluation of prescriber sales for pre-call planning from Account Summary Report
- Measure that the most valuable drivers of sales were detailed and sampled in accordance with the recommended call plan - account/physician –
  - o Average Calls per Day –reviews call activity against target or segmentation
  - o Reach and Frequency can be found on Analytics Tab.
  - o Call Plan information can be found on the Call Plan Tab
  - o Call Plan Analysis Report can be found on the Analytics Tab
- Measure the impact of detailing and sampling on Sales –
  - o Effort vs. Results Report can be found on the Analytics Tab
- Examine the landscape for the product to identify top sales accounts and potential
  - o Territory Sales Analysis—Reviews trends in client product and competitive landscape; can be found on Analytics Tab
  - o Territory Payer Analysis –Examines Payer information; can be found on Analytics Tab
  - o Territory Comparison Report—Compares sales performance at the territory level for all territories within span of control; can be found on Analytics Tab

While there is a suite of reports included in the Veeva offering, the reporting department is designed to create and publish ad hoc (one time) and custom (scheduled) reporting. These reports are scoped for time and resources and the fees are agreed to

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prior to any work being performed. Included in the Veeva offering are the following time period reports prepared at Territory level and rolled in summary to the district, regional and national level unless noted otherwise:

Table: Veeva Field Force Reporting Tools

Template Reports	Base Assumptions	Standard Frequency
Account Summary Report	<ul style="list-style-type: none"> <li>• Monthly Prescriber based product level sales data (from wholesalers)</li> </ul>	Monthly
Activity/Administrative Dashboard	<p>A. Reviews key territory and/or district performance indicators with drill down details for:</p> <ul style="list-style-type: none"> <li>• Interactions</li> <li>• Detailing</li> <li>• Sampling</li> </ul> <p>B. Review key territory and/or district administrative metrics with drill down details</p> <p>C. Any information collected within a check box or drop down list into the Veeva systems can be aggregated into a dashboard element.</p> <p>D. Text box information can be rolled into a report but not the dashboard.</p> <p>E. Dashboards can have up to 20 measurement elements</p> <p>F. All Dashboard elements are pictorials which aggregate data from an underlying report</p> <p>G. All pictorials are flexible but limited to two dimensions</p> <p>H. Color selection is not an option</p> <p>I. Filters can be applied to comparable data</p> <p>J. Reports can be filtered by user level (Field, Management, Home Office)</p> <p>K. Other Reportable Activity:</p> <ul style="list-style-type: none"> <li>• System Utilization</li> </ul>	Real Time as of last synchronization and refresh of widgets

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	<ul style="list-style-type: none"> <li>• Pending Interaction (Exception/incomplete information)</li> <li>• Time off Territory</li> <li>• Synchronization Reports</li> <li>• Interaction by Date and Time</li> <li>• Field Action Requests</li> <li>L. Account Demographics <ul style="list-style-type: none"> <li>• Target/Non-Target</li> <li>• Account Type (practitioner, pharmacy, staff, etc.)</li> <li>• Specialty</li> <li>• Segmentation</li> <li>• Custom Profile Attributes</li> </ul> </li> <li>M. Closed Loop Marketing (CLM) <ul style="list-style-type: none"> <li>• Slide Utilization as % of Calls</li> <li>• View Duration</li> <li>• Ranking of Slides by View count and Average Duration</li> <li>• Viewer Reaction (Positive, Neutral, Negative)</li> </ul> </li> </ul>	
Reach and Frequency	<ul style="list-style-type: none"> <li>• Adapted to specific activity measurements and goals within set up matrix (calls, targets only, reach, frequency, sample distribution)</li> </ul>	Real Time as of last synchronization and refresh
Average Calls Per Day Report	<ul style="list-style-type: none"> <li>• Average Calls Per Day versus goal</li> </ul>	Real Time as of last synchronization and refresh
Territory Sales Analysis Report	<ul style="list-style-type: none"> <li>• Adapted to specific product/market definition</li> <li>• Monthly Prescriber based product level sales data (from wholesalers); Up to 3 promoted products</li> </ul>	Monthly
Territory Comparison Report (Mgmt. supplement)	<ul style="list-style-type: none"> <li>• Adapted to specific product/market definition</li> <li>• Monthly Prescriber based product level sales data (from wholesalers); Up to 3 promoted products</li> <li>• Comparison of sales data amongst the assigned span of control</li> </ul>	Monthly

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Territory Payer Analysis	<ul style="list-style-type: none"> <li>• Monthly Payer based product level sales data (from wholesalers)</li> <li>• Analysis of the prescriber payer</li> <li>• Top Payers</li> <li>• Comparison of payer market products</li> </ul>	Monthly
Effort vs. Results aka Impact Report	<ul style="list-style-type: none"> <li>• Adapted to specific product/market definition</li> <li>• Up to 3 promoted products</li> <li>• Monthly Prescriber based product level sales data (from wholesalers)</li> </ul>	Monthly

### 3.5 Targeting & Call Plan Administration

inVentiv will provide Targeting and sales force alignment services for optimization of key customers. These services will produce the following:

- Optimize geographic coverage on the most valuable targets while balancing territory workload
- Target List generation based on business-specific workload parameters including the incorporation of any segmentation, detailing and frequency provided
- Identification of uncovered white space geography

Deliverables including:

- MSA Overview
- Alignment Summary including coverage of Top Targets
- Uncovered Geography Summary
- Mapping at Territory, District and National levels
- Zip-Terr
- Span Of Control
- Target List
- Updates/realignments to be provided every eighteen (18) months

The scope assumes the following:

- Alignment will be created utilizing inVentiv’s preferred alignment software
- Territory Workload parameters and project assumptions are agreed upon before work starts
- All Third Party Agreements are signed off on before work starts
- Third Party Data purchased by inVentiv will be passed through to Client
- Client will supply physician level universe which will include Best Address and any

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workload specific data points (Rx, Deciles, etc.)

Items not included in these assumptions:

- On-going realignments in addition to the 18-month realignment set forth above
- Managements sessions for alignment tweaks
- Additional mapping and data analysis

### **3.6 Incentive Compensation**

inVentiv will facilitate incentive compensation requirement /assessment meetings with the Client to establish plan parameters, data availability, budget, assess plan goals and bonus culture of Client. Additionally inVentiv will create a formal IC plan (“IC Plan”), subject to approval by Client in its sole discretion. Upon approval of the IC Plan by Client, such IC Plan will be distributed to the field force for signature and electronic validation of plan acceptance. The plan documentation will outline the plan payment components as well as terms and conditions for participation in the plan. IC results data will be calculated based on monthly data provided by Client. inVentiv will develop scorecards to document the field performance to the approved plan. Typically, field forces are paid bonus on a quarterly cycle which commences post the receipt of sales data for the final month of the quarter. Client will be provided with territory level results which aggregate to the national level. This allows for budget analysis, accrual processing and approval of results findings or adjustments to plan in the event of major windfalls or shortfalls outside the field control. Post concurrence of the performance results, inVentiv will process IC payouts through the inVentiv payroll system.

inVentiv will develop and administer the incentive compensation (“IC”) plan through the following phases:

#### **Plan Design:**

- Plan Design & Documentation:
- Plan Modeling & Design Factors
- Final Plan Documentation

#### **Implementation & Programming:**

- SQL Programming to implement IC Plan (Product Allocations, Goals, Sales Data processing, etc.)
- Report Programming & Scorecard Design
- Setup of User interface
- Programming QC & Testing

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- Validation & QC of IC programming & scorecard design (independent of Programming QC)
- Acknowledgement Portal Setup

**Ongoing Management & Maintenance:**

- Maintenance of IC Acknowledgement database
- Sales data processing
- Processing, QC & Distribution of IC Scorecards (Reps & Managers)
- Eligibility Processing

Deliverables and timelines are provided in the tables following:

**Design Phase**

Category	Description	Duration/Timeline
IC Plan Meeting (s)	Initial Meeting to discuss: <ul style="list-style-type: none"> <li>• Corporate Philosophy</li> <li>• Sales Goals/Objectives</li> <li>• Sales/Marketing Strategy</li> <li>• Business Rules</li> <li>• Data Inputs</li> <li>• Eligibility Requirements</li> </ul>	1 day – initial meeting; subsequent follow-up meetings may be held to discuss pending topics or matters requiring further discussion from initial meeting. <b>Maximum timeline 3 weeks</b>
IC Modeling	Based on inputs derived from initial IC meeting(s), inVentiv will create/provide IC deck illustrating: <ul style="list-style-type: none"> <li>• Recommended IC plan(s)</li> <li>• Payout Scenarios/Distribution</li> </ul>	<ul style="list-style-type: none"> <li>• 1 week to provide recommendation</li> <li>• 1 week for feedback/follow-up</li> <li>• Additional time may be needed if data is required for modeling</li> </ul>
Field Communication	IC Plan communication includes: <ul style="list-style-type: none"> <li>• PowerPoint deck (Management Team &amp; Sales force)</li> <li>• Word/PDF document (for plan participants/acknowledgement)</li> </ul>	3 weeks (maximum) once IC plan has been finalized.

**Implementation Phase:**

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Category	Description	Duration/Timeline
IC Plan Programming	<ul style="list-style-type: none"> <li>• Data Process Setup</li> <li>• SQL Programming</li> <li>• User Interface Setup</li> <li>• Report/Scorecard Programming</li> <li>• KPI/MBO Programming (if applicable)</li> <li>• Acknowledgement Portal Setup</li> <li>• Programming QC &amp; Testing</li> <li>• Validation &amp; QC of IC programming (independent of Programming QC)</li> <li>• Minor changes (cosmetic, etc.)</li> </ul>	Maximum of 3 weeks after receipt of initial sales data file

**Maintenance/Management Phase:**

Category	Description	Duration/Timeline
Plan Administration	IC Plan Processing <ul style="list-style-type: none"> <li>• Report Generation               <ul style="list-style-type: none"> <li>o Payout Grid/Summary</li> <li>o Scorecard</li> <li>o Management Summary</li> </ul> </li> <li>• IC QC</li> <li>• Report Distribution</li> <li>• Roster Management</li> <li>• Eligibility; LOA; PIP</li> <li>• Acknowledgment Portal Maintenance</li> </ul>	2 weeks after receipt of monthly sales data file

**3.7 Sales Administration**

**3.7.1 Fleet Management Services**

inVentiv will provide Fleet services for the Client project. The Fleet activities will be managed by a Fleet Analyst who will be responsible for the following:

- Tracking of and confirmation of background check for all employees in Fleet vehicles
- Management of vendor involvement for accidents, fuel cards, and insurance
- Coordination of delivery of bridge rentals or Fleet vehicles dependent upon background check completion, timeline of deployment and vehicle availability
- Recommendations for snow belt vehicles as applicable for project
- Flexibility of ordering new vehicles or transfer of existing surplus vehicles dependent upon team size, availability and Client budget
- Timely pick-up of vehicles through third-party vendor for terminations and LOAs as appropriate

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The associated timelines for the project assumes the following:

- Timely notification of territory and district locations for vehicle placement
- 8-week standard timeline for ordering of new vehicles
- Vehicles delivered upon first day of field deployment

### **3.7.2 Human Resources Management Services (Admin Support)**

inVentiv will provide HR services for the project to support the recruiting and ongoing field management requirements. The HR activities will be managed by an HR Manager who will be responsible for the following:

- Creation and distribution of offer letters, new hire checklist and return FedEx envelope to New Hire via FedEx
- Distribution of emails from Sterling InfoSystems to complete required data for background screening and drug screen
- Distribution of info regarding the New Hire Green Site to acknowledge reference documents, print new hire forms and send to HR
- Receipt and tracking of signed offer letter and new hire forms
- Tracking of background and drug screening results from Sterling (follow-up may be required)
- Conduct new hire orientation Webex on first day of employment or live at training
- Notification to Client of background issues
- Works with NBD/Project Lead for instances of PIP letters, investigations of compliance and other issues
- Coordination with Leave Administration on all state and federal leaves of absences
- Delivery of termination notices, participation in personnel calls regarding downsizing and conversions

The timelines for the project assumes the following:

- Timely completion of Sterling background link from new hires
- Information regarding vacation, bonus, expectations are available for inclusion in the offer letters

### **3.7.3 Field Operations Management**

The Operations Manager will be assigned and work with the Project Manager during the implementation period. Post-deployment, the Operations Manager will assume the day-to-day management of the project and will be responsible for the following:

- Management of inVentiv proprietary back-end system to interact with HR PeopleSoft for employee information and roster management

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- Population of territory information in back-end system, and coordination of rep to territory connections
- Work with third-party vendor for sourcing of meeting and training locations, if applicable. Provide support and coordination of travel and meeting planning services, either with Client vendor or as a stand-alone offering. On-site meeting support available as needed
- Timely notification of new hires, terminations, LOAs and address changes through launch and post-deployment to Client, vendors and internal team
- Responsible for monitoring project parameters and managing payout of incentive compensation within project guidelines
- Coordination of inVentiv operational department expectations, services and communications to field post-deployment
- Review of monthly invoicing and budgets for adherence to project P&L

The associated timelines for the project assumes the following:

- Timely receipt of territory names and numbers for inclusion in back-end system
- On-going notification of new hire information
- Participation in appropriate Client calls regarding launch meeting needs and training logistics
- Live training conducted at client facility or other location
- Coordination with Project Manager throughout implementation for transition timing of daily operational tasks

### **3.8 Travel & Expense Management (Concur Solution)**

inVentiv leverages the industry standard T&E system, Concur, for capturing of all expense management for reimbursement for and HCP data capture for inVentiv Employees for the Project. The Expense Management Solution will assume the following:

- Completion of Project Parameters and Expense Types worksheets for project set-up based on client spend limits and business rules (Business Rules to be Approved by client as part of project setup).
- Information on areas such as Amex cards, mileage rates, report approvers, etc. are communicated and decided on at onset of implementation based on Client business rules
- Standard Concur expense fields and set-up are used for project
- DME (Direct Marketing Expense) Data Extract for client tracking and reporting for Federal Sunshine and State requirements (per client requirements as documented in the Data Requirements Document)

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- Full-cycle testing of the DME File Delivery Process
- Coordination of Learning Management System (LMS) project set-up and communication of system access and viewing of Concur module to new hires/end users
- Inclusion of Expense Management in Technology Training sessions (Manager/Rep)
- Tracking of completed Concur module review in LMS per user

inVentiv will work closely with client in the Data Requirements process to confirm the file format, data elements, and file delivery process and frequency to meet Client specifications for Transparency Reporting and Client System Integration.

### **3.9 Field Support Services (Help Desk & Asset Management)**

#### Help Desk:

The inVentiv Field Service Desk supports inVentiv Systems and Operational processes, to ensure field user readiness and performance.

- Field Support Service Desk hours are Monday through Friday, 8am-10pm, Eastern Time
- Standard inVentiv metrics and KPIs for call and ticket resolution
- Field Support can be reached via telephone or via email
- Knowledge Base will be supplied for Service desk based on client business rules and system configuration
- Standard Monthly reporting will be provided along with Post-Rollout daily monitoring reporting for 2 weeks following each field deployment

#### Asset Management:

inVentiv will provide full asset management services ranging from hardware procurement to configuration and deployment and includes tracking IT assets throughout the life of the project. inVentiv maintains a suite of standard Windows images and custom images available as needed. Client hardware is asset tagged, scanned and secured in a locked area with restricted access for designated IT personnel.

Our standard hardware platform includes:

- Field Laptop with carrying case
- Apple iPad with folio cover and stylus
- Printer

Users are given inVentiv-hosted email boxes with the option to configure with client-like domains/addresses to give the look and feel of a Client employee.

inVentiv shall use commercially reasonable efforts to ship Repairs/replacements of broken, stolen or lost hardware one business day after receiving notification of such breakage, theft or loss.

Passcode-protected iPads are deployed using our Mobile Device Management software with remote-wipe capabilities for added security. App packaging and deployment capabilities are available. For clients opting for iPads with data plans, we can activate with one of the major carriers prior to shipment and then maintain that data plan throughout the life of the contract.

### **3.10 Sales Training Services**

inVentiv will provide training services for the inVentiv Sales Representatives including the development of a comprehensive training program and certification of all inVentiv field employees for the client project across the following areas and sources:

- o Scientific Materials and Product Training (client provided content)
- o RX Advantage Selling Skills (inVentiv provided content)
- o Compliance Training (inVentiv provided content)
- o Sales Management Training (inVentiv provided content)
- o Technology & Operational Training (inVentiv Health provided content)

inVentiv will leverage an internal Learning Management System (LMS) to consolidate all training curriculum and training records and allow tracking and reporting of certification internally and to client.

### **3.11 Quality Management and Assurance**

#### Quality Management System (QMS):

All Client implementations are managed via an approved set of Standard Operating Procedures (SOPs) which are part of inVentiv Health's Quality Management System (QMS) under the Director of Quality Assurance. Key processes such as Change Control, CRM Implementations of Third Party Applications and Training are required training for Sales Operations personnel. Other SOPs such as Security and Access Control, System Development Life Cycle, Asset Provisioning and CRM End-User Training are additional required training for implementation teams delivered and tracked within inVentiv's Learning Management System.

#### System Validation:

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Formal System Validation is conducted by professional validation resources following inVentiv Health's System Validation SOP. The work is driven by the approved Business Requirements Document (BRD), and includes a Validation Plan, Operational Qualification, Performance Qualification, Test Evidence (typically screen shots), Deviation Reports, Traceability Matrix and a Validation Summary Report.

### **3.12 Compliance Services**

#### Pre-Launch Activities:

- Initial interaction and fact finding with clients
- Development and consultation in regards to the implementation of client specific business rules
- Creation of all training materials, (home study on Learning Management System) and live training modules
- Work with and post specific policies required by the client, help develop SOP's if required

#### Launch Activities:

- Loading and testing of all on-line training to be conducted during home study, as well as assessments to test knowledge and competency. All tracking and reporting of results from the training.
- Live training to be conducted at launch meetings, POA's at client site's or in-house

#### Ongoing Activities:

- Training for all new hires/backfill for replacement personnel or expansions at client site's or in-house
- Continual monitoring and updating if guidelines, laws, state requirements, or client business rules change during the course of the year
- Corporate Integrity Agreement (CIA) obligations, additional training requirements, debarment of personnel, and annual certification of personnel and reporting to the client
- Updates and assistance in supplying the necessary oversight and training at POA meetings during the year
- Compliance/Representative ride-along program to monitor the field personnel in regards to their compliance requirements as agreed to by the client (Optional)

#### Enforcement and Monitoring:

- inVentiv adheres to an "Open Door Policy" and encourages employees to discuss issues and or concerns of misconduct with their manager or other senior personnel, Human

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Resources, or a member of the Compliance team

- inVentiv also encourages and supports a 24 hour anonymous hotline 7 days a week if the person making the report requires or wishes to remain anonymous
- inVentiv has an Investigation Policy in place so as to insure continuity in enforcement, and transparency with our personnel and clients so proper adjudication is achieved

#### 4.0 Change Control Process

Throughout the development of a business solution, additional knowledge is gained and situations and underlying assumptions change. A key component of the project management process is to identify the changes and make informed decisions, especially with regard to functionality, schedule and cost.

The change control process enables inVentiv and its customer to maintain a shared vision for the project. The objectives of change control are to:

- Assess the impact of scope changes on project schedules, resources and pricing
  - Provide a formal vehicle for approval to proceed with any changes to this Statement of Work
  - Provide a project audit record of all material changes to the original Statement of Work
- If requirements arise that are outside the scope of this proposal, a Change of Scope document will be submitted for client approval following the below process:

1. Client requests additional requirements for new functionality or deliverables outside the scope of work identified.
2. inVentiv reviews change, meets with client and internal team members to understand and scope client expectations regarding business need, timelines, and other deliverable expectations.
3. inVentiv provides Change of Scope document which outlines work effort, timeline and pricing impacts of the change. Pricing will be determined based on standard rates provided below.
4. Client accepts proposal and signs Change of Scope document which authorizes work to begin on the change request.

Standard Pricing Table:

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<b>Role</b>	<b>Price/HR</b>
Software Development	[†]
Data Management	[†]
Alignment/Call Planning	[†]
Incentive Comp Modeling/Design	[†]
Testing	[†]
Project Management	[†]
Analytics & Reporting	[†]
IC Administration	[†]
Training (Content/Delivery)	[†]
Hardware/Help Desk	[†]

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**EXHIBIT C**  
**COMPENSATION - FIXED FEES, VARIABLE FEES AND PASS-THROUGH COSTS**

**I. FIXED FEES**

(a) Implementation Fee

Client shall pay inVentiv \$307,922 for implementation fee associated with performance of the Services.

(b) Fixed Monthly Fee

Commencing on the date of hire of the first Project Team member Client shall pay inVentiv a Fixed Monthly Fee as follows:

<b>Period</b>	<b>Fixed Monthly Fee</b>
Year One	[†]
Year Two	[†]

For clarity, the Implementation Fee and Fixed Monthly Fee shall be the total compensation paid by Client to inVentiv for performing the Services. Unless expressly set forth herein, including in Section II of this Exhibit C, inVentiv shall be responsible for any costs associated with performing the Services.

(c) Salary Reconciliation

The parties agree that the Fixed Monthly Fees set forth in Section I (b), above, are based on the annual salary per inVentiv Sales Representative of \$[†] in Year One and \$[†] in Year Two (the “Annual Salary”). When calculated on a quarterly basis such salary shall be \$[†] in Year One and \$[†] for Year Two (the “Quarterly Salary”). inVentiv will reconcile such salaries (excluding incentive compensation) on a calendar quarter basis as follows: for each inVentiv Sales Representative, the applicable Quarterly Salary shall be multiplied by the ratio of (A) the aggregate actual days worked (as determined in accordance with inVentiv human resources policies then in effect) by such inVentiv Sales Representative in such calendar quarter to (B) the total working days in such calendar quarter (as determined in accordance with inVentiv human resources policies then in effect) (each a “Calculated Quarterly Salary”). The Parties agree that the Quarterly Salary does not include bonuses for the inVentiv Sales Representatives (or the applicable employer portion of taxes) for such calendar quarter. If such reconciliation shows that the inVentiv’s Calculated Quarterly Salary is below the Quarterly Salary for such Sales Representative, then inVentiv shall issue a credit (or, in the case of the final quarter of the Term,

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a payment) for the entire amount of such difference to Client within thirty (30) days of the close of such calendar quarter. If such reconciliation shows that inVentiv's Calculated Quarterly Salary is above the Quarterly Salary for such Sales Representative, then inVentiv shall bill the difference to Client. For clarity, any credits arising from a vacancy (whether such vacancy occurs before or after the Deployment Date) or for any Block Conversion will be calculated in accordance with Section I(d) below.

(d) Vacancy Credit; Block Conversion Credit

inVentiv agrees to fill vacant territories as requested by Client. inVentiv will continue to invoice Client the amounts set forth above as Fixed Monthly Fee during any such vacancy period. inVentiv will provide a monthly credit to Client, prorated for the number of business days per month that a territory is vacant, for each vacant territory that is vacant for a period of time that exceeds one (1) month, until such territory is filled, as set forth in the table below.

In addition, if Client exercises its rights to a Block Conversion in accordance with Section 5(b) of the Project Agreement, inVentiv will provide a monthly credit to Client for such Sales Representative(s) for the remainder of the Term, prorated for the month in which such Conversion takes place for the number of business days per month that such position has been Converted, as set forth in the table below.

	<b>Year One</b>	<b>Year Two</b>
<b>Monthly Vacancy or Block Conversion Credit</b>	[†]	[†]

**II. PASS-THROUGH COSTS**

In addition to the Fixed Fees and subject to the terms and conditions of the MSA and PA, including the remainder of this Section II, certain expenses will be charged to Client on a pass-through basis. These expenses will be billed to Client at actual cost. The categories of permissible pass-through costs are as follows:

- Bonuses for the inVentiv Sales Representatives (plus applicable employer portion of taxes)
- Project Team member travel expenses (e.g. transportation, lodging, meals, etc.)
- Costs for all meetings, including but not limited to POA Meetings
- Marketing and entertainment costs
- Sales TRx data and any third party data acquisition expenses
- Interview expenses
- Travel expenses for inVentiv recruiters
- Licensing and credentialing expenses
- Other expenses which have been approved by Client.

All meetings for which inVentiv may seek reimbursement shall be held only at Client's

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request, and all marketing costs are to be agreed-upon by the Parties. Any travel and entertainment expenses shall be subject to inVentiv's travel and entertainment policies and procedures. Without the prior written approval of Client, Client shall not be responsible for reimbursement for any travel or entertainment expenses in excess of or in violation of any applicable inVentiv travel and entertainment policies and procedures reviewed and approved by Client.

### **III. INVOICES; BILLING TERMS**

The Implementation Fee shall be paid in full on or before June 30, 2014. Up to but not exceeding one (1) month of Fixed Monthly Fee shall be invoiced to Client by inVentiv upon the Deployment Date, provided, however, that inVentiv shall, unless such amount has been credited to Client against subsequent Fixed Monthly Fees owed to Client, repay to Client any such amount paid to inVentiv by Client upon the termination or expiration of this Agreement. Commencing in the month of the Deployment Date, Client will be billed monthly on the first day of the month the amount stated above as the Fixed Monthly Fee. For purposes of clarity, the intent is that inVentiv should receive payment of the Fixed Monthly Fee on the first day of the month for which the payment applies (e.g., payment received June 1 for June activities), and in no event shall Client be charged a Fixed Monthly Fee more than once for a given month. Pass-through Costs will be billed to Client at actual cost as incurred by inVentiv.

Except as set forth in the preceding paragraph, payments are due within thirty (30) days of Client's receipt of each applicable invoice from inVentiv. If an invoice is not paid within thirty (30) days of Client's receipt, inVentiv reserves the right to impose a finance charge of the lesser of 1.0% (calculated on a monthly basis) or the maximum amount permitted by law of all amounts due.

### **IV. RECORDS AND AUDITS**

During the Term and for a period of three (3) years thereafter, inVentiv shall keep and maintain complete and accurate records regarding matters relevant to payment of fees or other compensation under this Project Agreement (including records of the number of days worked by inVentiv Sales Representatives, pass-through costs, bonus compensation or incentive compensation). Upon Client's request and at Client's expense, inVentiv shall permit an independent certified public accounting firm selected by Client and reasonably acceptable to inVentiv to have access during normal business hours to inVentiv's records as necessary to determine the correctness and completeness of such records and the amounts paid in accordance with such records. Such audit shall not take place more than twice a year. If such audit concludes that additional payments were owed or that excess payments were made during such period, the owing Party shall pay the additional payments or the receiving Party shall reimburse such excess payments, within sixty (60) days after the date on which such accounting firm's written report is delivered to the Parties. Each Party shall cooperate with such accounting firm's investigation, and the results of any investigation under this Section IV shall be made available to both Parties and be deemed the confidential information of both Parties, with both Parties the Disclosing Party and Receiving Party with respect thereto. Notwithstanding the foregoing, if any

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such audit discloses a variance to the detriment of Client of more than [†] percent ([†]%) from the amount of the original payment calculation, inVentiv shall bear the reasonable and documented cost of such audit.

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**FIRST AMENDMENT TO  
PROJECT AGREEMENT  
(Detailing and Sales Operations Services)**

This First Amendment (the "Amendment") dated June 13, 2014 (the "Effective Date") is made by and between Ventiv Commercial Services, LLC, with an office at 500 Atrium Drive, Somerset, N.J. 08873 ("inVentiv") and Omeros Corporation, with an office at 201 Elliott Avenue West, Seattle, WA 98119 (referred to herein as the "Client"). inVentiv and Client may each be referred to herein as a "Party" and, collectively, as the "Parties."

**W I T N E S S E T H:**

**WHEREAS**, inVentiv and Client are parties to a Project Agreement (Detailing and Sales Operation Services) made as of May 12, 2014 (the "Agreement").

**WHEREAS**, inVentiv and Client desire to amend the Agreement as set forth herein.

**NOW THEREFORE**, in consideration of the premises and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, it is agreed as follows:

1. Except as provided in this Amendment, the terms and conditions set forth in the Agreement shall remain unaffected by execution of this Amendment. To the extent any provisions or terms set forth in this Amendment conflict with the terms set forth in the Agreement, the terms set forth in this Amendment shall govern and control. Terms not otherwise defined herein, shall have the meanings set forth in the Agreement.

2. The Parties acknowledge and agree that, prior to the Deployment Date, inVentiv will be responsible for providing credit cards to all inVentiv Sales Representatives who establish credit-worthiness in accordance with standards established by American Express. Client and inVentiv shall establish appropriate limitations on the amount of available credit. In the event an inVentiv Sales Representative is unable to establish credit worthiness, Client shall determine if it nevertheless desires to have a credit card issued to such inVentiv Sales Representative. All credit card expenses shall be submitted and processed through the inVentiv expense reimbursement system. In the event of a default on a credit card invoice by any inVentiv Sales Representative, Client shall reimburse inVentiv for all obligations resulting from such default that are related to legitimate pass through costs chargeable to Client under the Agreement.

3. This Amendment may be executed simultaneously in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. Execution and delivery of this Amendment by exchange of facsimile copies or via pdf file bearing the facsimile signature of a party hereto shall constitute a valid and binding execution and delivery of this Amendment by such party. Such facsimile copies and/or pdf versions shall constitute enforceable original documents.

4. The terms of this Amendment are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and may not be contradicted by evidence of any prior or contemporaneous agreement. The Parties further intend that this Amendment constitute the complete

and exclusive statement of its terms and shall supersede any prior agreement with respect to the subject matter hereof.

**WHEREFORE**, the parties hereto have caused this Amendment to be executed by their duly authorized representatives.

**OMEROS CORPORATION      VENTIV COMMERCIAL SERVICES, LLC**

By: /s/ Gregory A. Demopulos      By: /s/ Theodore Wong  
Name: Gregory A. Demopulos, M.D.      Name: Theodore Wong  
Title: Chairman and CEO      Title: VP & CFO  
Date: 6/30/14      Date: 7/2/2014

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

	For the six months ended June 30,	Year Ended December 31,				
		<u>2014</u>	<u>2013</u>	<u>2012</u>	<u>2011</u>	<u>2010</u>
(in thousands)						
<b>Earnings before fixed charges:</b>						
Loss from continuing operations before income taxes	\$ (34,633)	\$ (39,796)	\$ (38,444)	\$ (28,546)	\$ (29,251)	\$ (21,089)
Add fixed charges	3,289	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	<u>\$ (31,344)</u>	<u>\$ (34,175)</u>	<u>\$ (36,139)</u>	<u>\$ (26,402)</u>	<u>\$ (27,147)</u>	<u>\$ (18,493)</u>
<b>Fixed Charges:</b>						
Interest expense	\$ 1,258	\$ 1,865	\$ 1,355	\$ 1,532	\$ 1,328	\$ 1,948
Amortization of debt expense and loss from extinguishment of debt	352	502	374	352	503	254
Estimate of interest expense within rental expense	1,679	3,254	576	260	273	394
Preference security dividend requirements of consolidated subsidiaries	—	—	—	—	—	—
Total fixed charges	<u>\$ 3,289</u>	<u>\$ 5,621</u>	<u>\$ 2,305</u>	<u>\$ 2,144</u>	<u>\$ 2,104</u>	<u>\$ 2,596</u>
Deficiency of earnings available to cover fixed charges	\$ (34,633)	\$ (39,796)	\$ (38,444)	\$ (28,546)	\$ (29,251)	\$ (21,089)

**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. Demopoulos, 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: August 11, 2014

/s/ Gregory A. Demopoulos

Gregory A. Demopoulos, M.D.  
Principal Executive Officer

**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: August 11, 2014

/s/ Michael A. Jacobsen

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Michael A. Jacobsen

Principal Financial and Accounting Officer

**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 June 30, 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: August 11, 2014

/s/ Gregory A. Demopoulos

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Gregory A. Demopoulos, M.D.  
Principal Executive Officer

**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 June 30, 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: August 11, 2014

/s/ Michael A. Jacobsen

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Michael A. Jacobsen

Principal Financial and Accounting Officer

