OMEROS CORP
Form 10-Q
May 10, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2016
or
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission file number: 001-34475

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

Washington	91-1663741
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
201 Elliott Avenue West Seattle, Washington	98119
(Address of principal executive offices)	(Zip Code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

As of May 2, 2016, the number of outstanding shares of the registrant's common stock, par value $0.01 per share, was 39,135,054.

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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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act, which are subject to the "safe harbor" created by those sections for such statements. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than statements of historical fact are "forward-looking statements." Terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "may," "plan," "potential," "predict," "project," "shoul 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 plans for sales, marketing and distribution of OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3%;
- our expectations regarding our product sales and our estimate regarding how long our existing cash, cash equivalents, short-term investments and revenues will be sufficient to fund our anticipated operating expenses, capital expenditures and interest and principal payments on our outstanding notes under our Loan and Security Agreement, or the Oxford/EWB Loan Agreement, with Oxford Finance LLC, or Oxford, and East West Bank, or EWB;
- our ability to raise additional capital through the capital markets, including under our at-the-market equity facility with JonesTrading Institutional Services LLC, or JonesTrading, or through one or more corporate partnerships, equity offerings, debt financings, collaborations, licensing arrangements or asset sales;
- our ability to forecast accurately wholesaler demand as well as our estimates of chargebacks and rebates, distribution fees and estimated product returns;
- our ability to enter into acceptable arrangements with potential corporate partners, including with respect to OMIDRIA;
- our expectations regarding the clinical, therapeutic and competitive benefits of OMIDRIA and our product candidates;
- our anticipation that we will rely on contract manufacturers to manufacture OMIDRIA for commercial sale and to manufacture our product candidates and our expectations regarding product supply and manufacturing of OMIDRIA;
- our expectations about the commercial competition that OMIDRIA and our product candidates, if commercialized, may face;
- our expectation that the OMIDRIAssure™ Reimbursement Services Program will increase patient access to OMIDRIA;
- 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;
- when or whether the dosing limitations in our OMS824 program may be removed;
- our ability to design and successfully complete clinical trials and other studies for our products and product candidates and our plans and expectations regarding our clinical trials, including our clinical trials for OMS721 and for OMS824;
- the expected course and costs of existing claims, legal proceedings and administrative actions, our involvement in potential claims, legal proceedings and administrative actions, and the potential outcomes and effects of both existing and potential claims, legal proceedings and administrative actions, as well as regulatory determinations, on our business, prospects, financial condition and results of operations;
- our expectations regarding our OMS103 exclusive license agreement including, without limitation, the manufacturing and commercialization of OMS103 and the commencement and subsequent continuation of product sales on which we could receive royalty revenue; and
- our expected financial position, performance, revenues, growth, expenses, magnitude of net losses and the availability of resources.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item IA of Part II of this Quarterly Report on Form 10-Q under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our other filings with the Securities and Exchange Commission, or SEC. Given these risks, uncertainties and other factors, actual results or anticipated developments may not be realized or, even if substantially realized, may not have the expected consequences to or effects on our company, business or operations. Accordingly, you should not place undue reliance on these forward-looking statements, which represent our estimates and

assumptions only as of the date of the filing of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual results in subsequent periods may materially differ from current expectations. Except as required by applicable

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law, including the securities laws of the United States and the rules and regulations of the SEC, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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PART I—FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS
OMEROS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(unaudited)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$978	$ 1,365
Short-term investments	12,266	26,898
Receivables	6,646	6,517
Inventory	1,972	472
Prepaid expense	2,460	1,894
Total current assets	24,322	37,146
Property and equipment, net	898	951
Restricted cash and investments	10,679	10,679
Other assets	73	219
Total assets	$35,972	$ 48,995
Liabilities and shareholders' deficit		
Current liabilities:		
Accounts payable	$5,332	$ 6,428
Accrued expenses	12,120	9,752
Current portion of notes payable	69	73
Total current liabilities	17,521	16,253
Notes payable, net	49,973	49,769
Deferred rent	9,220	9,207
Commitments and contingencies (Note 8)		
Shareholders' deficit:		
Preferred stock, par value $0.01 per share, 20,000,000 authorized and none issued and outstanding at March 31, 2016 and December 31, 2015	—	—
Common stock, par value $0.01 per share, 150,000,000 authorized at March 31, 2016 and December 31, 2015; 39,119,154 and 38,040,891 issued and outstanding at March 31, 2016 and December 31, 2015, respectively	391	380
Additional paid-in capital	382,548	376,528
Accumulated deficit	(423,681)	(403,142)
Total shareholders' deficit	(40,742)	(26,234)
Total liabilities and shareholders' deficit	$35,972	$ 48,995

See notes to condensed consolidated financial statements

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OMEROS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues		
Product sales, net	$7,246	$238
Grant revenue	173	150
Total revenue	7,419	388
Costs and expenses		
Cost of product sales	327	11
Research and development	15,434	9,318
Selling, general and administrative	11,110	8,989
Total costs and expenses	26,871	18,318
Loss from operations	(19,452)	(17,930)
Interest expense	(1,375)	(957)
Other income (expense), net	288	218
Net loss	$(20,539)	$(18,669)
Comprehensive loss	$(20,539)	$(18,669)
Basic and diluted net loss per share	$(0.54)	$(0.51)
Weighted-average shares used to compute basic and diluted net loss per share	38,317,084	36,483,559

See notes to condensed consolidated financial statements

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OMEROS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(unaudited)

	Three Months Ended March 31,	
	2016	2015
Operating activities:		
Net loss	$(20,539)	$(18,669)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	53	55
Stock-based compensation expense	4,422	2,517
Non-cash interest expense	213	212
Changes in operating assets and liabilities:		
Receivables	(129)	(146)
Inventory	(1,500)	—
Prepaid expenses and other noncurrent assets	(420)	725
Accounts payable and accrued expenses	1,272	(2,170)
Net cash used in operating activities	(16,628)	(17,476)
Investing activities:		
Purchases of investments	(18)	(79,389)
Proceeds from the sale and maturities of investments	14,650	17,300
Net cash provided by (used in) investing activities	14,632	(62,089)
Financing activities:		
Proceeds from issuance of common stock and pre-funded warrants, net	—	79,076
Proceeds upon exercise of stock options and warrants	1,609	1,576
Net cash provided by financing activities	1,609	80,652
Net (decrease) increase in cash and cash equivalents	(387)	1,087
Cash and cash equivalents at beginning of period	1,365	354
Cash and cash equivalents at end of period	$978	$1,441
Supplemental cash flow information		
Cash paid for interest	$776	$745

See notes to condensed consolidated financial statements

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OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

We are a biopharmaceutical company committed to discovering, developing and commercializing both small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system. Our first drug product OMIDRIA was approved by the United States (U.S.) Food and Drug Administration (FDA) for use during cataract surgery or intraocular lens replacement. We broadly launched OMIDRIA in the U.S. in April 2015.

Basis of Presentation

Our condensed consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions have been eliminated and we have determined we operate in one segment. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of March 31, 2016 and for the three months ended March 31, 2016 and 2015 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2015 has been derived from our audited financial statements but does not include all of the information and footnotes required by GAAP.

The accompanying unaudited condensed consolidated financial statements and related notes thereto should be read in conjunction with the audited consolidated financial statements and related notes thereto that are included within our Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 15, 2016.

Product Sales, Net

We record revenue from OMIDRIA product sales when the product is delivered to our wholesalers.

Product sales are recorded net of estimated chargebacks and rebates, wholesaler distribution fees and estimated product returns. Accruals or allowances are established for these deductions when revenue is recognized, and actual amounts incurred are offset against the applicable accruals and allowances. We reflect each of these accruals or allowances as either a reduction in the related accounts receivable or as an accrued liability, depending on how the accrual or allowance is settled.

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.

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Liquidity and Capital Resources

As of March 31, 2016, we had $13.2 million in cash, cash equivalents and short-term investments. In addition, we have $10.0 million in restricted cash and investments that must be maintained in depository and investment accounts pursuant to the Loan and Security Agreement (the Oxford/EWB Loan Agreement) entered into in December 2015 with Oxford Finance LLC (Oxford) and East West Bank (EWB) as well as $679,000 used to secure a letter of credit for the Omeros Building lease. We expect to continue to incur losses until such time as OMIDRIA product sales, corporate partnerships and/or licensing revenues from products or programs are adequate to support our ongoing operating expenses and debt service. We are unable to predict if or when this may occur, and until it does occur, we will need to continue to raise additional funds through public or private equity securities sales, including under our At Market Issuance Sales Agreement (the ATM Agreement) with JonesTrading Institutional Services LLC (JonesTrading) (see Note 9 for further detail), through the incurrence of additional debt, through corporate partnerships, through asset sales or through the pursuit of collaborations and licensing arrangements related to certain of our products or programs. These conditions raise a substantial doubt about our ability to continue as a going concern. If we are unable to become cash-flow positive or to raise additional capital as and when needed, or upon acceptable terms, such failure would have a significant negative impact on our financial condition.

The accompanying unaudited condensed consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying unaudited condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Recently Adopted Accounting Pronouncements

For the year ended December 31, 2015 we adopted and applied retrospectively Financial Accounting Standards Board (FASB) Accounting Standards Update, or ASU, No. 2015-03, related to simplifying the presentation of debt issuance costs. This standard requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction to the liability. The adoption of ASU 2015-03 resulted in the reclassification of $226,000 of debt issuance costs in our March 31, 2015 Condensed Consolidated Statement of Cash Flows.

Recent Accounting Pronouncements

In February 2016, FASB issued ASU 2016-02 related to lease accounting. This standard requires lessees to recognize a right-of-use asset and a lease liability for most leases. This standard must be applied using a modified retrospective transition and is effective for all annual and interim periods beginning after December 15, 2018. Earlier adoption is permitted. We are evaluating how this new standard will impact the presentation of our financial statements and related disclosures.

In March 2016, FASB issued ASU 2016-08 related to revenue recognition. This standard is an amendment to ASU 2014-09 relating to revenue from contracts with customers. This amendment clarifies an entity’s revenue recognition for a performance obligation based on principal versus agent considerations. 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. As amended, the standard is effective for interim and annual periods beginning after December 15, 2017 and cannot be adopted before that effective date. We are currently evaluating the impact that this standard may have on our financial statements once it is adopted.

In March 2016, the FASB issued ASU 2016-09 that changes the accounting for certain aspects of share-based payments to employees. The guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid in capital pools. The guidance also allows for the employer to repurchase more of an employee’s shares for tax withholding purposes without triggering liability accounting and for making a policy election to account for forfeitures as they occur rather than on an estimated basis. The guidance is effective for interim and annual periods beginning after December 15, 2016 with early adoption permitted. We are currently evaluating the impact that this standard may have on our financial statements once it is adopted and the timing of adoption.

Note 2—Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common share equivalents outstanding for the period, determined using the treasury-stock method.

The basic and diluted net loss per share amounts for the three months ended March 31, 2016 and 2015 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:

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	March 31,	
	2016	2015
Outstanding options to purchase common stock	9,302,348	8,365,741
Warrants and pre-funded warrants to purchase common stock	—	1,160,788
Total	9,302,348	9,526,529

Note 3—Cash, Cash Equivalents and Investments

As of March 31, 2016 and December 31, 2015, all investments are classified as short-term and available-for-sale on the accompanying Condensed Consolidated Balance Sheets. We did not own any securities with unrealized loss positions as of March 31, 2016 or December 31, 2015. Investment income, which is included as a component of other income (expense), consists of interest earned.

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 they are developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

Our fair value hierarchy for our financial assets and liabilities measured at fair value on a recurring basis are as follows:

	March 31, 2016			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	$10,679	$ —	$ —	$10,679
Money-market funds classified as short-term investments	12,266	—	—	12,266
Total	$22,945	$ —	$ —	$22,945

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
	(In thousands)			
Assets:				
Money-market funds classified as non-current restricted cash and investments	$10,679	$ —	$ —	$10,679
Money-market funds classified as short-term investments	26,898	—	—	26,898
Total	$37,577	$ —	$ —	$37,577

Cash held in demand deposit accounts of $978,000 and $1.4 million is excluded from our fair-value hierarchy disclosure as of March 31, 2016 and December 31, 2015, respectively. There were no unrealized gains and losses associated with our short-term investments as of March 31, 2016 or December 31, 2015. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets for 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.

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Note 5—Inventory

The components of inventory are as follows:

	March 31, 2016	December 31, 2015
	(In thousands)	
Raw materials	$104	$ 93
Work-in-process	1,692	158
Finished goods	176	221
Total inventory	$1,972	$ 472

Work-in-process consists of manufactured vials of OMIDRIA which have not been packaged into finished goods.

Note 6—Accrued Liabilities

Accrued liabilities consisted of the following:

	March 31, 2016	December 31, 2015
	(In thousands)	
Contract research and development	$3,260	$ 2,973
Consulting and professional fees	3,232	2,400
Employee compensation	2,544	2,590
Clinical trials	2,061	1,108
Other accruals	1,023	681
Total accrued liabilities	$12,120	$ 9,752

Note 7—Notes Payable

In December 2015, we entered into the Oxford/EWB Loan Agreement pursuant to which we borrowed $50.0 million. We can also borrow an additional $20.0 million in two tranches of $10.0 million each through June 30, 2017, contingent upon the satisfaction of certain conditions including minimum net revenues from OMIDRIA. The Oxford/EWB Loan Agreement requires interest-only payments through July 1, 2017. Beginning in August 2017, principal and interest payments are due through the January 1, 2020 maturity date.

The Oxford/EWB Loan Agreement contains covenants that require us to maintain $10.0 million in restricted cash and certain eligible term investments and limit or restrict our ability to enter into certain transactions. In addition, we are required to either meet an annual OMIDRIA net revenue minimum for 2016 of $70.0 million and quarterly OMIDRIA revenue minimums in 2017 and 2018, or maintain 50% of the then-outstanding note payable balance in restricted cash and certain eligible term investments. The Oxford/EWB Loan Agreement also includes provisions related to events of default, the occurrence of a material adverse effect (MAE) and changes of control. The occurrence of an event of default could result in the acceleration of the Oxford/EWB Loan Agreement and, under certain circumstances, could increase our interest rate by 5.0% per annum during the period of default. There was no event of default under the Oxford/EWB Loan Agreement as of March 31, 2016.

As of March 31, 2016, the remaining unamortized discount and debt issuance costs associated with the debt were $3.6 million and $414,000, respectively.

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Note 8—Commitments and Contingencies

Development Milestones and Product Royalties

We have retained control of worldwide commercial rights to OMIDRIA, to all of our product candidates and to our programs other than OMS103. We may be required, in connection with existing in-licensing or asset acquisition agreements, to make certain royalty and milestone payments and we cannot, at this time, determine when or if the related milestones will be achieved or whether the events triggering the commencement of payment obligations will occur. See Note 9 to our Consolidated Financial Statements for the year ended December 31, 2015 included within our Annual Report on Form 10-K as filed with the SEC on March 15, 2016.

Litigation

As described within Note 9 of the “Notes to Consolidated Financial Statements” included within our Annual Report on Form 10-K for the year ended December 31, 2015 filed with the SEC on March 15, 2016, we filed a patent infringement lawsuit against Par Pharmaceutical, Inc. and its subsidiary, Par Sterile Products, LLC (collectively, Par) following our receipt of a Paragraph IV Notice Letter from Par stating Par is seeking approval from the FDA to market a generic version of OMIDRIA. During 2016, we amended the lawsuit asserting an additional OMIDRIA patent, which was granted by the U.S. Patent and Trademark Office after Par filed its original Paragraph IV Notice Letter. We have filed suit against Par, thereby triggering a stay which is expected to remain in effect until January 2018 of the FDA’s final approval of Par’s ANDA. We continue to believe that the assertions in Par’s Paragraph IV Notice Letter do not have merit and we intend to prosecute vigorously our patent infringement claims against Par.

Note 9—Shareholders’ Equity

Common Stock

At Market Issuance Sales Agreement - In January 2016, we entered into the ATM Agreement with JonesTrading pursuant to which we may direct JonesTrading to sell shares of our common stock with an aggregate offering price of up to $100.0 million directly on The Nasdaq Global Market, through a market maker other than on an exchange or in negotiated transactions. Any sales made under the ATM Agreement are based solely on our instructions and JonesTrading will receive a 1.7% commission from the gross proceeds. The ATM Agreement may be terminated by either party at any time upon 10 days' notice to the other party or by JonesTrading at any time in certain circumstances including the occurrence of a material adverse effect to Omeros.

Securities Offering - In February 2015, we sold 3.4 million shares of our common stock at a public offering price of $20.03 per share and sold pre-funded warrants to purchase up to 749,250 shares of our common stock at a public offering price of $20.02 per pre-funded warrant share. The public offering price for the pre-funded warrants was equal to the public offering price of our common stock, less the $0.01 per share exercise price of each pre-funded warrant. After deducting underwriter discounts and offering expenses of $4.9 million, we received net proceeds from the offering of $79.1 million.

Warrants

For the three months ended March 31, 2016, we received cash proceeds of approximately $7,500 upon the cash exercise of our then-outstanding pre-funded warrants, which had a weighted average exercise price of $0.01 per share, that resulted in the issuance of 749,250 shares of our common stock.

For the three months ended March 31, 2015, we received proceeds of $1.4 million upon the exercise of warrants to purchase approximately 126,000 shares of our common stock.

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Note 10—Stock-Based Compensation

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

	Three Months Ended March 31,	
	2016	2015
	(In thousands)	
Research and development	$2,155	$1,324
Selling, general and administrative	2,267	1,193
Total	$4,422	$2,517

In February 2016, in connection with our annual employee review process, we granted qualified employees options to purchase approximately 1.3 million shares of our common stock with an exercise price of $10.27.

The fair value of each option grant to employees and directors is estimated on the date of grant using the Black-Scholes option-pricing model. The following assumptions were applied to employee and director stock option grants during the periods ended:

	Three Months Ended March 31,	
	2016	2015
Estimated weighted-average fair value	$6.62	$13.49
Weighted-average assumptions		
Expected volatility	74 %	70 %
Expected term, in years	5.7	6.0
Risk-free interest rate	1.44 %	1.51 %
Expected dividend yield	— %	— %

Stock option activity for all stock plans and related information is as follows:

	Options Outstanding	Weighted-Average Exercise Price per Share	Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Balance at December 31, 2015	8,310,235	$ 7.97		
Granted	1,349,055	10.31		
Exercised	(329,013)	4.87		
Forfeited	(27,929)	14.51		
Balance at March 31, 2016	9,302,348	$ 8.40	6.54	$ 65,720
Vested and expected to vest at March 31, 2016	9,012,412	$ 8.30	6.46	$ 64,505
Exercisable at March 31, 2016	6,486,712	$ 7.09	5.50	$ 53,722

At March 31, 2016, excluding non-employee stock options, the total estimated compensation expense to be recognized in connection with our unvested options is $16.6 million and 2,189,575 shares were available to grant.

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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 both small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, coagulopathies and disorders of the central nervous system.

Our marketed drug product OMIDRIA® (phenylephrine and ketorolac injection) 1%/0.3% was broadly launched in the U.S. in April 2015 for use during cataract surgery or intraocular lens, or IOL, replacement. OMIDRIA is derived from our proprietary PharmacoSurgery® platform, which is designed to improve clinical outcomes of patients undergoing ophthalmological, arthroscopic, urological and other surgical procedures. Our proprietary PharmacoSurgery platform is based on low-dose combinations of U.S. Food and Drug Administration-approved, or 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.

In our pipeline we have clinical-stage development programs focused on: complement-related thrombotic microangiopathies; complement-mediated glomerulopathies; Huntington's disease and cognitive impairment; addictive and compulsive disorders; and problems associated with urologic surgical procedures. In addition, we have a diverse group of preclinical programs and 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, other than OMS103, we have retained control of all commercial rights.

Products, Product Candidates, Development Programs and Platforms

OMIDRIA. OMIDRIA is approved in the U.S. by the FDA for use during cataract surgery or IOL replacement to maintain pupil size by preventing intraoperative miosis (pupil constriction) and to reduce postoperative ocular pain, and is approved in all European Union, or EU, member states plus Iceland, Lichtenstein and Norway for use during cataract surgery and other IOL replacement procedures to maintain mydriasis (pupil dilation), to prevent miosis (pupil constriction), and to reduce postoperative eye pain. We broadly launched OMIDRIA in the U.S. in April 2015 primarily through wholesalers which, in turn, sell to ambulatory surgery centers, or ASCs, and hospitals. The Centers for Medicare and Medicaid Services, or CMS, has granted transitional pass-through reimbursement status for OMIDRIA, which we expect to run until January 1, 2018. Pass-through status allows for separate payment (i.e., outside the bundled payment) under Medicare Part B for new drugs and other medical technologies that meet well-established criteria specified by federal regulations governing Medicare spending. In January 2016, we announced the results of certain investigator-initiated studies of OMIDRIA that demonstrate statistically significant reduction in small pupil-associated complication rates, in usage of costly pupil-expanding devices and in age-adjusted surgical times together with statistically significant improvement in uncorrected visual acuity on the day after surgery and in prevention of miosis during femtosecond laser-assisted surgery; these outcomes are not referenced in the currently approved labeling for OMIDRIA.

In May 2016, we entered into an exclusive supply and distribution agreement with ITROM Trading Drug Store, or ITROM, for the sale of OMIDRIA in the Kingdom of Saudi Arabia, the United Arab Emirates and certain other countries in the Middle East. Within the licensed territory, ITROM is responsible for obtaining marketing authorizations for OMIDRIA, on our behalf, and for promoting, marketing, selling and distributing product supplied by us. We expect ITROM will begin selling OMIDRIA later this year.

OMS103. OMS103, derived from our PharmacoSurgery platform, was developed for use during all arthroscopic procedures, including knee and shoulder arthroscopy, and completed Phase 3 trials in patients undergoing arthroscopic anterior cruciate ligament reconstruction and arthroscopic partial meniscectomy. In June 2015, we entered into an exclusive licensing agreement, or the OMS103 Agreement, with Fagron Compounding Services, LLC, d/b/a Fagron Sterile Services, and JCB Laboratories, LLC, or collectively Fagron, an FDA-registered human drug outsourcing facility, under which Fagron is obligated to produce under Good Manufacturing Practices, or GMP, and to

commercialize OMS103 in the U.S. Fagron has not performed its performance diligence obligations under the OMS103 Agreement, including initiating sales, and we are currently evaluating our options regarding the OMS103 Agreement and our OMS103 program.

Product Candidates. We have a pipeline of development programs targeting immune-related disorders, pain, inflammation, coagulopathies and disorders of the central nervous system. We have the following clinical-stage programs in our pipeline:

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- MASP-2 - OMS721. OMS721, our lead MASP-2 antibody, is being developed for diseases in which the lectin pathway, one of the principal complement activation pathways, which is believed to contribute to significant tissue injury and pathology. One group of such diseases is thrombotic microangiopathies, or TMAs, including atypical hemolytic uremic syndrome, or aHUS, thrombotic thrombocytopenic purpura, or TTP, and hematopoietic stem-cell transplant, or HSCT, -related TMA. We recently initiated an OMS721 Phase 3 clinical program that consists of one single-arm (i.e., no control arm), open-label trial in patients with newly diagnosed or ongoing aHUS and we expect enrollment will begin later this year. We are also currently conducting two Phase 2 clinical programs, one in patients with other TMAs (i.e., HSCT-related TMA and TTP), as well as a second Phase 2 clinical program in patients with immunoglobulin A, or IgA, nephropathy and other complement-related renal diseases (e.g., membranous nephropathy, lupus nephritis and C3 glomerulopathy) in which we recently initiated patient dosing in a Phase 2 clinical trial in corticosteroid-dependent renal diseases. In addition, in February 2016, we announced that Finnish physicians had requested access to OMS721 under a Special License, granted by the Finnish regulatory authorities, to treat a patient with aHUS who was previously treated with Soliris® (eculizumab) but was determined to not have an adequate response and who was continuing to display signs of active aHUS.
- PDE10 - OMS824 for Huntington's disease and Schizophrenia. OMS824, our lead phosphodiesterase 10, or PDE10, inhibitor, is in a Phase 2 clinical program for the treatment of Huntington's disease, in which clinical trials are currently subject to dosing limitations, and a Phase 2 clinical program for schizophrenia, in which no clinical trials are currently active. The dosing limitations in our Phase 2 clinical trial in Huntington's may potentially be removed pending generation, submission and FDA review of additional information. We are conducting nonclinical studies to generate additional data for further discussion with the FDA regarding the dosing limitations and are currently preparing for a re-designed Phase 2 clinical trial in patients with Huntington's disease. As we announced in October 2014, clinical trials evaluating OMS824 in schizophrenia are suspended currently at the request of the FDA. Given that there was no active schizophrenia trial at the time of program suspension, the FDA will address the OMS824 schizophrenia program when we have a related trial protocol ready for initiation.
- PPAR - OMS405. In our peroxisome proliferator-activated receptor gamma, or PPAR , program, Phase 2 clinical trials have been conducted by our collaborators to evaluate a PPAR agonist, alone or in combination with other agents, for treatment of addiction to opioids and to nicotine. Our collaborators are analyzing data from these trials and expect to present relevant information in manuscripts to be published at a later date.
- OMS201-Urology. OMS201, our PharmacoSurgery product candidate for use during urological procedures, including uroendoscopic procedures, completed a Phase 1/Phase 2 clinical trial in 2010 and is not currently in active clinical trials.

Development Programs and Platforms. Our preclinical programs and platforms include:

- PDE7 - OMS527. In our PDE7 program, we are developing proprietary compounds to treat addiction and compulsive disorders as well as movement disorders.
- Plasmin - OMS616. In our Plasmin program, 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).
- MASP-3 - OMS906. In our MASP-3 program, OMS906, we are developing MASP-3 inhibitors for the treatment of disorders related to the alternative pathway of the complement system and currently are optimizing potent and functionally active antibodies in preparation for scale-up of one or more clinical candidates.
- GPCR Platform and Programs. We have developed a proprietary cellular redistribution assay, or CRA, which we use in a high-throughput manner to identify synthetic ligands, including antagonists, agonists and inverse agonists, that bind to and affect the function of orphan GPCRs. We are conducting in vivo preclinical efficacy studies and optimizing compounds for a number of targets including: GPR17, linked to myelin formation; GPR101, linked to appetite and eating disorders; GPR151, linked to neuropathic pain and cognition; GPR161, which is associated with triple negative breast cancer; GPR183, linked to osteoporosis and to Epstein-Barr virus infections and related diseases; and GPR174, which appears to be involved in the modulation of regulatory T cells, or "T-regs," known to be important in autoimmune disease, such as multiple sclerosis, and in cancer and organ transplantation.
- Antibody Platform. Our proprietary ex vivo platform for the discovery of novel, high-affinity monoclonal antibodies, which was in-licensed from the University of Washington and then further developed by our scientists, utilizes a

chicken B-cell lymphoma cell line. We have generated antibodies to several clinically significant targets, including highly potent antibodies against MASP-3, and our platform continues to add to our pipeline antibodies against additional important targets.

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Financial Summary

We recognized net losses of $20.5 million and $18.7 million for the three months ended March 31, 2016 and 2015, respectively. As of March 31, 2016, our accumulated deficit was $423.7 million, total shareholders' deficit was $40.7 million and we had $13.2 million in cash, cash equivalents and short-term investments available for general corporate use. In addition, we had restricted cash and investments of $10.7 million that we are required to maintain in depository and investment accounts pursuant to (a) our Loan and Security Agreement, or the Oxford/EWB Loan Agreement, with Oxford Finance LLC, or Oxford, and East West Bank, or EWB, and (b) our lease related to the Omeros Building.

Results of Operations

Revenue

Our revenue consists of U.S. product sales of OMIDRIA and revenue recognized in connection with third-party grant funding.

	Three Months Ended March 31,	
	2016	2015
	(In thousands)	
Product sales, net	$7,246	$238
Small Business Innovative Research Grants (SBIR)	173	150
Total revenue	$7,419	$388

The quarterly increase in product sales, net during the three months ended March 31, 2016 compared to the quarterly periods in 2015 was due to the growth in U.S. OMIDRIA sales following our limited product launch in February 2015 and the subsequent broad launch in April 2015. The 9% increase in product sales, net during the three months ended March 31, 2016 compared to the three months ended December 31, 2015 was lower than the growth rate of our prior quarter, which we believe can be attributed to a variety of factors. Effective January 1, 2016, we converted our contract sales force to an in-house sales force, resulting in the replacement of approximately one-third of our previously contracted sales representatives. During January we also hired additional replacement representatives and entered into a commission-only contract sales agent agreement with Precision Lens to cover "square" states in the Midwest that were not covered by our existing sales force. Our newly hired replacement representatives and the Precision Lens representatives completed training programs during January and began making sales calls in early to mid-February, and the average OMIDRIA sales cycle continues to be 10-12 weeks. In addition, January and February have several ophthalmic meetings that are well attended by high-volume cataract surgeons and Medicare data show that the first quarter of any year is generally associated with an 8% reduction in cataract surgery procedures relative to other quarters in the year. While sales were restrained in the first half of the quarter, they subsequently accelerated with March accounting for nearly one half of our first quarter OMIDRIA sales.

Gross-to-Net Deductions

We record OMIDRIA product sales net of estimated chargebacks, rebates, distribution fees and product returns. These deductions are generally referred to as gross-to-net deductions. A summary of our gross-to-net accrual for the three months ended March 31, 2016 is as follows:

	Chargebacks and Rebates	Distribution Fees and Product Return Allowances	Total
	(In thousands)		
Balance as of December 31, 2015	$180	$ 277	$457
Provision related to current period sales	285	268	553

Payments made/credits granted	(220)	(189)	(409)
Balance as of March 31, 2016	$245	$ 356	$601

Our overall Omidria gross-to-net deduction for the quarter ended March 31, 2016 was 7.1% of gross product sales.

Chargebacks and Rebates. Subsequent to March 31, 2015, we entered into a variety of agreements including a Pharmaceutical Pricing Agreement, a Federal Supply Schedule, or FSS, agreement, a 340B prime vendor agreement and a Medicaid Drug Rebate Agreement which allow eligible entities to receive discounts on their qualified purchases of OMIDRIA.

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We record a provision for estimated chargebacks and rebates related to these agreements at the time of sale and reduce the accrual when payments are made or credits are granted.

In October 2015, we launched the OMIDRIAssure Reimbursement Services Program to expand patient access to OMIDRIA. We record a provision for estimated OMIDRIAssure claims at the time of sale and reduce the accrual when payments are made.

We expect future chargeback and rebate deductions as a percentage of gross Omidria product sales to increase based on our 340B prime vendor agreement, the increased use of OMIDRIAssure and increased volume of purchases eligible for government-mandated discounts such as 340B and FSS, and rebates.

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

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

We expect distribution fees and product return allowances to correlate to changes in product sales.

Research and Development Expenses

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

The following table illustrates our expenses associated with these activities:

	Three Months Ended March 31,	
	2016	2015
	(In thousands)	
Direct external expenses:		
Clinical research and development:		
OMS721	$5,996	$1,233
OMIDRIA (OMS302)	1,266	754
OMS824	272	532
Other clinical programs	15	17
Total clinical research and development	7,549	2,536
Preclinical research and development	488	501
Total direct external expenses	8,037	3,037
Internal, overhead and other expenses	5,242	4,957
Stock-based compensation expense	2,155	1,324
Total research and development expenses	$15,434	$9,318

The increase in total clinical research and development expenses during the three months ended March 31, 2016 compared to the same period in 2015 is due primarily to increased costs for our OMS721 program in connection with clinical manufacturing and other clinical research and development activities. Additional increases included clinical

trial costs for OMIDRIA due to continued enrollment and clinical site initiations for the post-approval U.S. pediatric study. This increase was offset by lower clinical research and development costs related to our OMS824 program due to its 2014 clinical suspension.

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In addition, stock-based compensation expenses increased during the three months ended March 31, 2016 compared to the same period in 2015 related to annual company-wide option grants approved in February 2016 with April 1, 2015 vesting commencement dates.

We anticipate that total research and development costs will remain steady or increase slightly during the remainder of this year due to planned clinical manufacturing and clinical study activities relating primarily to OMS721, subject to increases in OMIDRIA product sales and raising of additional funds to support our planned development activities.

At this time, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates due to the inherently unpredictable nature of our preclinical and clinical development activities and given the early stage of many of our preclinical development programs. Clinical development timelines, the probability of success and development costs can differ materially as new data become available and as expectations change. While we are focused currently on advancing our product development programs, our future research and development expenses will depend, in part, on the preclinical or clinical success of each product candidate as well as ongoing assessments of each program's commercial potential. Our future research and development expenses will also be affected by the availability of adequate financial resources and the commercial success of OMIDRIA. In addition, we cannot forecast with any degree of certainty which product candidates, if any, may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

We are required to expend substantial resources in the development of our product candidates due to the lengthy process of completing clinical trials and seeking regulatory approval. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could delay our generation of product revenue and increase our research and development expenses 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 or if we would recognize any net cash inflows from our research and development projects.

Selling, General and Administrative Expenses

	Three Months Ended March 31,	
	2016	2015
	(In thousands)	
Selling, general and administrative expenses, excluding stock-based compensation expense	$8,843	$7,796
Stock-based compensation expense	2,267	1,193
Total selling, general and administrative expenses	$11,110	$8,989

The increase in selling, general and administrative expenses during the three months ended March 31, 2016 compared to the same period in 2015 was primarily due to increased legal costs associated with the Par lawsuit, increased administrative costs, and increased selling related activities. The increase in stock-based compensation expense during the three months ended March 31, 2016 compared to the same period in the prior year was due to annual company-wide option grants approved in February 2016 with April 1, 2015 vesting commencement dates.

We anticipate selling, general and administrative costs will increase slightly during the remainder of this year primarily due to commissions on our third party sales agent agreements for OMIDRIA and legal costs in connection with enforcing our patents and pursuing our patent infringement claims related to Par's effort to obtain FDA approval for a generic version of OMIDRIA.

Interest Expense

Three Months Ended March 31,	
2016	2015

	(In thousands)	
Interest expense	$1,375	$957

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The increase in interest expense during the three months ended March 31, 2016 compared to the same quarter in the prior year was due to the increase in our outstanding notes payable balance under the Oxford/EWB Loan Agreement during the comparative periods.

Other Income (Expense), Net

	Three Months Ended March 31,	
	2016	2015
	(In thousands)	
Other income (expense), net	$288	$218

Other income (expense), net principally includes sublease rental income and interest earned. The increase during the three months ended March 31, 2016 compared to the prior year quarter was due to incremental sublease income earned.

Financial Condition - Liquidity and Capital Resources