

OMEROS CORP
Form 10-Q
May 10, 2018
Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018

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 (I.R.S. Employer
incorporation or organization) Identification Number)

201 Elliott Avenue West 98119
Seattle, Washington (Address of principal executive offices) (Zip Code)
(206) 676-5000
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

Emerging growth company

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

Exchange Act.

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

As of May 7, 2018, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 48,292,608.

Table of Contents

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,” “likely,” “may,” “plan,” “potential,” “predict,” “project,” “would,” and similar expressions and variations thereof are intended to identify forward-looking statements, but these terms are not the exclusive means of identifying such statements. Examples of these statements include, but are not limited to, statements regarding:

- our expectations relating to demand for OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% from wholesalers, ambulatory surgery centers, or ASCs, and hospitals, and our expectations regarding OMIDRIA product sales, including once pass-through reimbursement status is reinstated pursuant to the Consolidated Appropriations Act, 2018, or the Appropriations Act;

- our estimates of OMIDRIA chargebacks and rebates, distribution fees and product returns;

- our estimates regarding how long our existing cash, cash equivalents, short-term investments and revenues will be sufficient to fund our anticipated operating expenses and capital expenditures, as well as our interest and principal payments on our outstanding notes under our Term Loan Agreement, or the CRG Loan Agreement, with CRG Servicing LLC, or CRG, and the lenders identified therein, and the satisfaction of covenants thereunder;

- our expectations with respect to additional funding under the CRG Loan Agreement;

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

- our expectations related to obtaining permanent separate or similar reimbursement for OMIDRIA from the Centers for Medicare and Medicaid Services, or CMS, and/or from Congress, including after September 30, 2020;

- our ability to design, initiate and/or successfully complete clinical trials and other studies for our products and product candidates and our plans and expectations regarding our clinical trials, including our clinical trials for OMS721, for OMS906 and for OMS527;

- in our OMS721 program, our expectations regarding: whether enrollment in any or all ongoing and planned Phase 3 clinical trials will proceed as expected; whether accelerated approval, fast track designation, breakthrough therapy designation and/or orphan drug designation may be granted by the U.S. Food and Drug Administration, or FDA, or Priority Medicines status, conditional marketing authorization or orphan designation may be granted by the European Medicines Agency, or EMA, for indications for which we are pursuing such approval or designation; whether and when a Biologics License Application, or BLA, for accelerated approval of OMS721 may be filed with the FDA; paths to accelerated and full approval of OMS721 in hematopoietic stem cell transplant-associated thrombotic microangiopathy, or HSCT-TMA; and potential approval with respect to our Phase 3 clinical trial for patients with Immunoglobulin A, or IgA, nephropathy;

- our anticipation that we will rely on contract manufacturers to manufacture OMIDRIA for commercial sale and to manufacture our product candidates for clinical trial supply and, if approved, for commercial sale;

- our ability to enter into acceptable arrangements with potential corporate partners or contract service providers, including with respect to OMIDRIA, and our ability and plans to effect any such arrangement with respect to OMIDRIA in the European Union, or EU, and to place OMIDRIA on the market (i.e., released into the distribution chain) in at least one European Economic Area country prior to July 28, 2018 to preserve OMIDRIA marketing authorization in Europe;

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

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

- the expected course and costs of existing claims, legal proceedings and administrative actions, our involvement in potential claims, legal proceedings and administrative actions, and the merits, potential outcomes and effects of both

existing and potential claims, legal proceedings and administrative actions, as well as regulatory determinations, on our business, prospects, financial condition and results of operations, including but not limited to our patent infringement lawsuits against Sandoz, Inc., or Sandoz, and against Lupin Ltd. and Lupin Pharmaceuticals, Inc., which we refer to collectively as Lupin;

Table of Contents

• 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;

• the factors on which we base our estimates for accounting purposes and our expectations regarding the effect of changes in accounting guidance or standards on our operating results; and

• our expected financial position, performance, revenues, growth, costs and expenses, magnitude of net losses and the availability of resources.

Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks, uncertainties and other factors described in Item 1A of Part 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 law, we assume no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

Table of Contents

OMEROS CORPORATION
FORM 10-Q FOR THE QUARTER ENDED March 31, 2018
INDEX

| | Page |
|--|-----------|
| <u>Part I — Financial Information</u> | <u>3</u> |
| <u>Item 1. Financial Statements (unaudited)</u> | <u>3</u> |
| <u>Condensed Consolidated Balance Sheets</u> | <u>3</u> |
| <u>Condensed Consolidated Statements of Operations and Comprehensive Loss</u> | <u>4</u> |
| <u>Condensed Consolidated Statements of Cash Flows</u> | <u>5</u> |
| <u>Notes to Condensed Consolidated Financial Statements</u> | <u>6</u> |
| <u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> | <u>13</u> |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u> | <u>22</u> |
| <u>Item 4. Controls and Procedures</u> | <u>22</u> |
| <u>Part II — Other Information</u> | <u>23</u> |
| <u>Item 1. Legal Proceedings</u> | <u>23</u> |
| <u>Item 1A. Risk Factors</u> | <u>23</u> |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u> | <u>37</u> |
| <u>Item 6. Exhibits</u> | <u>37</u> |
| <u>Signatures</u> | <u>38</u> |

Table of Contents

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, 2018 | December 31, 2017 |
|---|-------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 1,189 | \$ 3,394 |
| Short-term investments | 71,625 | 80,355 |
| Receivables, net | 182 | 17,144 |
| Inventory | 247 | 443 |
| Prepaid expense | 5,441 | 7,036 |
| Total current assets | 78,684 | 108,372 |
| Property and equipment, net | 2,081 | 2,121 |
| Restricted investments | 5,835 | 5,835 |
| Advanced payments, non-current | 2,435 | — |
| Total assets | \$ 89,035 | \$ 116,328 |
| Liabilities and shareholders' deficit | | |
| Current liabilities: | | |
| Accounts payable | \$ 10,183 | \$ 6,691 |
| Accrued expenses | 13,934 | 19,126 |
| Current portion of lease financing obligations | 513 | 490 |
| Total current liabilities | 24,630 | 26,307 |
| Notes payable and lease financing obligations, net | 85,037 | 84,117 |
| Deferred rent | 8,583 | 8,718 |
| Commitments and contingencies (Note 7) | | |
| Shareholders' deficit: | | |
| Preferred stock, par value \$0.01 per share, 20,000,000 shares authorized and none issued and outstanding at March 31, 2018 and December 31, 2017, respectively | — | — |
| Common stock, par value \$0.01 per share, 150,000,000 authorized; 48,286,842 and 48,211,226 issued and outstanding at March 31, 2018 and December 31, 2017 respectively | 483 | 482 |
| Additional paid-in capital | 523,724 | 520,072 |
| Accumulated deficit | (553,422) | (523,368) |
| Total shareholders' deficit | (29,215) | (2,814) |
| Total liabilities and shareholders' deficit | \$ 89,035 | \$ 116,328 |
| See accompanying Notes to Condensed Consolidated Financial Statements | | |

Table of Contents

OMEROS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(unaudited)

| | Three Months Ended | |
|--|--------------------|------------|
| | March 31, | |
| | 2018 | 2017 |
| Revenue: | | |
| Product sales, net | \$ 1,588 | \$ 12,257 |
| Costs and expenses: | | |
| Cost of product sales | 203 | 271 |
| Research and development | 18,140 | 12,240 |
| Selling, general and administrative | 10,934 | 12,471 |
| Total costs and expenses | 29,277 | 24,982 |
| Loss from operations | (27,689) | (12,725) |
| Interest expense | (2,825) | (2,663) |
| Other income | 460 | 299 |
| Net loss | \$(30,054) | \$(15,089) |
| Comprehensive loss | \$(30,054) | \$(15,089) |
| Basic and diluted net loss per share | \$(0.62) | \$(0.34) |
| Weighted-average shares used to compute basic and diluted net loss per share | 48,284,019 | 43,828,572 |
| See accompanying Notes to Condensed Consolidated Financial Statements | | |

Table of Contents

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

| | Three Months Ended March 31, | |
|---|---------------------------------|------------|
| | 2018 | 2017 |
| Operating activities: | | |
| Net loss | \$(30,054) | \$(15,089) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 2,966 | 3,276 |
| Non-cash interest expense | 1,086 | 995 |
| Depreciation and amortization | 223 | 115 |
| Changes in operating assets and liabilities: | | |
| Receivables | 16,962 | (1,444) |
| Inventory | 196 | 168 |
| Prepaid expenses and other assets | (840) | (1,494) |
| Accounts payable, accrued expenses and other | (1,835) | 771 |
| Net cash used in operating activities | (11,296) | (12,702) |
| Investing activities: | | |
| Purchases of property and equipment | (183) | (72) |
| Purchases of investments | (270) | (1,042) |
| Proceeds from the sale and maturities of investments | 9,000 | 11,778 |
| Net cash provided by investing activities | 8,547 | 10,664 |
| Financing activities: | | |
| Proceeds upon exercise of stock options | 687 | 1,147 |
| Payments on lease financing obligations | (143) | (51) |
| Net cash provided by financing activities | 544 | 1,096 |
| Net decrease in cash and cash equivalents | (2,205) | (942) |
| Cash and cash equivalents at beginning of period | 3,394 | 2,224 |
| Cash and cash equivalents at end of period | \$1,189 | \$1,282 |
| Supplemental cash flow information | | |
| Cash paid for interest | \$1,739 | \$1,667 |
| Conversion of accrued interest to notes payable | \$838 | \$805 |
| Property acquired under capital lease | \$— | \$70 |
| See accompanying Notes to Condensed Consolidated Financial Statements | | |

Table of Contents

OMEROS CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1—Organization and Significant Accounting Policies

Organization

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

Basis of Presentation

Our condensed consolidated financial statements include the financial position and results of operations of Omeros Corporation (Omeros) and our wholly owned subsidiaries. All inter-company transactions have been eliminated and we have determined we operate in one segment. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. The information as of March 31, 2018 and for the three months ended March 31, 2018 and 2017 includes all adjustments, which include normal recurring adjustments, necessary to present fairly our interim financial information. The Condensed Consolidated Balance Sheet at December 31, 2017 has been derived from our audited financial statements but does not include all of the information and footnotes required by GAAP for audited annual financial information. The accompanying unaudited condensed consolidated financial statements and related notes thereto should be read in conjunction with the audited consolidated financial statements and related notes thereto that are included in our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the U.S. Securities and Exchange Commission (SEC) on March 1, 2018.

Going Concern

On an interim and annual basis we are required to assess our ability to continue as a going concern for one year after the date the financial statements are issued using rules defined by ASC No. 205-40 - Going Concern (the Standard). As required by the Standard, management's evaluation shall initially not take into consideration the potential mitigating effects of management's plans that have not been fully implemented as of the date the financial statements are issued. In the second step of this evaluation, management's assumptions and plans are derived according to restrictions and definitions in the Standard. As such, for purposes of this exercise, the following assumptions (which are discussed in further detail following this summary) were made:

Limited cash receipts from sales of OMIDRIA. Even though we have received an extension of transitional pass-through reimbursement for OMIDRIA for a period of two years beginning October 1, 2018, we are unable at this time to predict accurately revenue from sales of OMIDRIA once transitional pass-through reimbursement begins. In addition, sales of OMIDRIA are generally made with 90-day collection terms and, therefore, minimal OMIDRIA cash receipts were included for this exercise prior to January 2019;

No additional draws on our CRG debt facility. As disclosed in Note 6, we are in compliance with all covenants under our CRG Loan Agreement and have requested the additional \$45.0 million that is available to us through May 20, 2018 subject only to customary closing conditions. However, given the existence of customary closing conditions, the draw on this facility was not considered for purposes of this exercise; and

No public or private equity transactions or partnering revenues can be considered for purposes of this exercise in the absence of any existing or committed arrangements to raise additional capital or of any existing or consummated partnerships.

In performing the first step of the assessment, we concluded that the following conditions raise substantial doubt about our ability to meet our financial obligations as they become due. As of March 31, 2018, we had \$72.8 million in cash, cash equivalents and short-term investments, \$0.2 million of accounts receivable and \$24.6 million in current liabilities. We have a history of net losses (\$30.1 million for the three months ended March 31, 2018 and \$53.5

million in 2017) and use of cash for operations (\$11.3 million for the three months ended March 31, 2018 and \$36.2 million in 2017). In addition, on January 1, 2018, transitional pass-through reimbursement for our only commercial product, OMIDRIA, which allowed for separate payment (i.e., outside the packaged procedural payment) under Medicare Part B expired and is not scheduled to be reinstated until October 1, 2018.

-6-

Table of Contents

In performing the second step of this assessment, we are required to evaluate whether our plans to mitigate the conditions above alleviate the substantial doubt about our ability to meet our obligations as they become due within one year after the date the financial statements are issued. In performing this second step of the assessment, we are limited to those assumptions listed above and the restrictions and definitions in the Standard. As such, we did not consider any future sources of working capital that we may otherwise be able to access such as the additional \$45.0 million available under our existing CRG Loan Agreement, which we have requested and expect to receive on May 18, 2018. Consequently, based on this assessment performed using the associated limitations required by the Standard, we have concluded there is substantial doubt about our ability to continue as a going concern through May 10, 2019. If we are unable to raise additional equity, debt or partnering capital when needed through one or more of the avenues previously listed, or upon acceptable terms, such failure would have a significant negative impact on our financial condition. Should it be necessary to manage our operating expenses, we would reduce our projected cash requirements through reduction of our expenses by delaying clinical trials, reducing selected research and development efforts, or implementing other restructuring activities.

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

Revenue Recognition

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) 2014-09 (Topic 606) "Revenue from Contracts with Customers," which requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. We adopted Topic 606 on January 1, 2018 using the modified retrospective transition method.

Once we determine that an arrangement is within the scope of Topic 606 and we believe it is probable that we will collect the consideration we are entitled to in exchange for OMIDRIA product sales, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Upon adoption, we evaluated our contracts with customers and determined the adoption of the standard did not change the timing or the amounts of our previously recognized revenues.

Product Sales, Net

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

The Centers for Medicare and Medicaid Services (CMS) granted transitional pass-through reimbursement status for OMIDRIA through December 31, 2017. Pass-through status for OMIDRIA allowed for reimbursement payment to Ambulatory Surgery Centers (ASCs) and hospitals using OMIDRIA in procedures involving patients covered by Medicare Part B. In March 2018, the Consolidated Appropriations Act, 2018 (the Appropriations Act) was signed into law, which among other things extended pass-through reimbursement status for certain drugs, including OMIDRIA, for a two-year period beginning October 1, 2018. For the period January 1, 2018 through September 30, 2018, OMIDRIA is not subject to reimbursement payment for procedures involving patients covered by Medicare Part B.

Advanced Payments

We have various agreements with third parties that require us to pay part of the contractually due amounts in advance of receiving goods and services. These agreements relate primarily to clinical and manufacturing activities. Amounts paid in advance of services to be delivered to us beyond 12 months of the balance sheet date are recorded as non-current assets.

-7-

Table of Contents

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant items subject to such estimates include revenue recognition, stock-based compensation expense and accruals for clinical trials, manufacturing of drug product and clinical drug supply and contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; however, actual results could differ from these estimates.

Recently Adopted Pronouncements

We adopted ASU 2018-05 issued by the FASB in March 2018 related to the Tax Cuts and Jobs Act (Tax Act) that was enacted in December 2017. We remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21.0%. The standard requires that we record and disclose any provisional amounts related to the Tax Act. We recorded and disclosed the provisional impact to our deferred tax balance in our Annual Report on Form 10-K for the year ended December 31, 2017 that was filed with the SEC on March 1, 2018. However, we are still analyzing certain aspects of the Tax Act, which could potentially affect the measurement of these assets and liabilities or potentially give rise to new deferred tax assets and liabilities.

In May 2016, the FASB issued ASU 2017-09 related to stock-based compensation, which provides clarity and consistency in practice on the accounting for changes to the terms and conditions of stock-based payment arrangement, or modifications. We adopted the guidance January 1, 2018 and the adoption did not have a material impact on our stock-based compensation expense.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02 related to lease accounting. The new 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 method and is effective for all annual and interim periods beginning after December 15, 2018. Earlier adoption is permitted. While we are still in the process of evaluating the effect of adoption on our consolidated financial statements and are currently assessing our leases, we expect to adopt the standard on January 1, 2019. We estimate the adoption of this standard will result in recognition of additional net lease assets and lease liabilities primarily due to the lease agreements for our office building and equipment financing leases.

Note 2—Net Loss Per Share

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

The basic and diluted net loss per share amounts for the three months ended March 31, 2018 and 2017 were computed based on the shares of common stock outstanding during the respective periods. Potentially dilutive securities excluded from the diluted loss per share calculation are as follows:

| | March 31, | |
|---|-----------|------------|
| | 2018 | 2017 |
| Outstanding options to purchase common stock | 9,640,452 | 10,924,062 |
| Outstanding warrants to purchase common stock | 100,602 | 100,602 |
| Total | 9,741,054 | 11,024,664 |

Table of Contents

Note 3—Accounts Receivable, Net

Accounts receivable, net consist of the following:

| | March 31, 2018 | December 31, 2017 |
|--------------------------------|----------------------|-------------------------|
| | (In thousands) | |
| Trade receivables, net | \$49 | \$ 17,079 |
| Sublease and other receivables | 133 | 65 |
| Total accounts receivables net | \$ 182 | \$ 17,144 |

Note 4—Fair-Value Measurements

As of March 31, 2018 and December 31, 2017, all investments were classified as short-term and available-for-sale on the accompanying Condensed Consolidated Balance Sheets. Investment income, which was included as a component of other income, consists of interest earned.

On a recurring basis, we measure certain financial assets at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The accounting standard establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available. The following summarizes the three levels of inputs required:

Level 1—Observable inputs for identical assets or liabilities, such as quoted prices in active markets;

Level 2—Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3—Unobservable inputs in which little or no market data exists, therefore they are developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

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

| | March 31, 2018 | | | |
|--|-------------------|---------|---------|-----------|
| | Level 1 | Level 2 | Level 3 | Total |
| | (In thousands) | | | |
| Assets: | | | | |
| Money-market funds classified as non-current restricted cash and investments | \$5,835 | \$ — | — | —\$5,835 |
| Money-market funds classified as short-term investments | 71,625 | — | — | 71,625 |
| Total | \$77,460 | \$ — | — | —\$77,460 |
| | | | | |
| | December 31, 2017 | | | |
| | Level 1 | Level 2 | Level 3 | Total |
| | (In thousands) | | | |
| Assets: | | | | |
| Money-market funds classified as non-current restricted cash and investments | \$5,835 | \$ — | — | —\$5,835 |
| Money-market funds classified as short-term investments | 80,355 | — | — | 80,355 |
| Total | \$86,190 | \$ — | — | —\$86,190 |

Cash held in demand deposit accounts of \$1.2 million and \$3.4 million is excluded from our fair-value hierarchy disclosure as of March 31, 2018 and December 31, 2017, respectively. There were no unrealized gains or losses associated with our short-term investments as of March 31, 2018 or December 31, 2017. The carrying amounts reported in the accompanying Condensed Consolidated Balance Sheets for receivables, accounts payable, other current monetary assets and liabilities and notes payable and lease financing obligations approximate fair value.

Table of Contents

Note 5—Accrued Liabilities

Accrued liabilities consist of the following:

| | March 31, 2018 | December 31, 2017 |
|---------------------------------------|----------------|-------------------|
| | (In thousands) | |
| Contract research and development | \$4,763 | \$ 4,251 |
| Employee compensation | 3,727 | 2,178 |
| Sales rebates, fees and discounts | 1,825 | 6,561 |
| Consulting and professional fees | 1,494 | 1,758 |
| Clinical trials | 1,118 | 1,026 |
| ASC/hospital product return liability | — | 2,350 |
| Other accruals | 1,007 | 1,002 |
| Total accrued liabilities | \$13,934 | \$ 19,126 |

Note 6—Notes Payable and Lease Financing Obligations

Notes payable and lease financing obligations consist of the following:

| | March 31, 2018 | December 31, 2017 |
|---|----------------|-------------------|
| | (In thousands) | |
| Notes payable | \$84,669 | \$ 83,831 |
| Lender facility fee payable upon maturity | 4,233 | 4,192 |
| Lease financing obligations | 1,180 | 1,300 |
| Notes payable, facility fee and lease financing obligations | 90,082 | 89,323 |
| Unamortized debt discount | (3,400) | |