DURECT CORP
Form 10-Q
May 03, 2013
**Table of Contents**

# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

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

**For the quarterly period ended March 31, 2013**

**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 000-31615**

# DURECT CORPORATION

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **94-3297098** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |

**10260 Bubb Road**

**Cupertino, California 95014**

**(Address of principal executive offices, including zip code)**

**(408) 777-1417**

**(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 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 a check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition 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 ¨ | 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 April 30, 2013, there were 101,894,463 shares of the registrant s Common Stock outstanding.

**Table of Contents**

**INDEX**

Table of Contents

## PART I. FINANCIAL INFORMATION

**Item 1. Financial Statements**

### DURECT CORPORATION

### CONDENSED BALANCE SHEETS

**(in thousands)**

| | March 31, 2013 (unaudited) | December 31, 2012 (Note 1) |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 8,250 | $ 11,195 |
| Short-term investments | 16,261 | 17,337 |
| Accounts receivable (net of allowances of $149 at March 31, 2013 and $154 at December 31, 2012) | 1,567 | 2,166 |
| Inventories | 3,058 | 3,399 |
| Prepaid expenses and other current assets | 1,949 | 2,258 |
| Total current assets | 31,085 | 36,355 |
| Property and equipment (net of accumulated depreciation of $20,209 and $19,956 at March 31, 2013 and December 31, 2012, respectively) | 2,229 | 2,457 |
| Goodwill | 6,399 | 6,399 |
| Intangible assets, net | 31 | 36 |
| Long-term investments | 716 | |
| Long-term restricted investments | 300 | 400 |
| Other long-term assets | 148 | 288 |
| Total assets | $ 40,908 | $ 45,935 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 833 | $ 1,785 |
| Accrued liabilities | 3,591 | 3,997 |
| Contract research liabilities | 423 | 483 |
| Deferred revenue, current portion | 255 | 662 |
| Total current liabilities | 5,102 | 6,927 |
| Deferred revenue, non-current portion | 1,487 | 1,480 |
| Other long-term liabilities | 791 | 1,197 |
| Commitments | | |
| Stockholders equity: | | |
| Common stock | 10 | 10 |
| Additional paid-in capital | 378,040 | 375,658 |
| Accumulated other comprehensive income | 4 | 6 |
| Accumulated deficit | (344,526) | (339,343) |
| Stockholders equity | 33,528 | 36,331 |
| Total liabilities and stockholders equity | $ 40,908 | $ 45,935 |

The accompanying notes are an integral part of these financial statements.

Table of Contents

**DURECT CORPORATION**

**CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**

**(in thousands, except per share amounts)**

**(unaudited)**

| | Three months ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Collaborative research and development and other revenue (see Note 2) | $ 913 | $ 38,328 |
| Product revenue, net | 3,240 | 2,857 |
| Total revenues | 4,153 | 41,185 |
| Operating expenses: | | |
| Cost of product revenues | 1,658 | 1,461 |
| Research and development | 4,789 | 5,634 |
| Selling, general and administrative | 2,901 | 3,280 |
| Total operating expenses | 9,348 | 10,375 |
| Income (loss) from operations | (5,195) | 30,810 |
| Other income (expense): | | |
| Interest and other income | 14 | 21 |
| Interest expense | (2) | (2) |
| Net other income | 12 | 19 |
| Net income (loss) | $ (5,183) | $ 30,829 |
| Net income (loss) per share | | |
| Basic | $ (0.05) | $ 0.35 |
| Diluted | $ (0.05) | $ 0.35 |
| Weighted-average shares used in computing net income (loss) per share | | |
| Basic | 101,881 | 87,547 |
| Diluted | 101,881 | 87,568 |
| Total comprehensive income (loss) | $ (5,181) | $ 30,826 |

The accompanying notes are an integral part of these financial statements.

Table of Contents

**DURECT CORPORATION**

**CONDENSED STATEMENTS OF CASH FLOWS**

**(in thousands)**

**(unaudited)**

| | Three months ended March 31, | |
|---|---|---|
| | **2013** | **2012** |
| **Cash flows from operating activities** | | |
| Net income (loss) | $ (5,183) | $ 30,829 |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | |
| Depreciation and amortization | 258 | 205 |
| Stock-based compensation | 945 | 1,176 |
| Changes in assets and liabilities: | | |
| Accounts receivable | 599 | 533 |
| Inventories | 341 | 16 |
| Prepaid expenses and other assets | 449 | 315 |
| Accounts payable | (952) | (659) |
| Accrued and other liabilities | 626 | (699) |
| Contract research liabilities | (60) | (696) |
| Deferred revenue | (400) | (35,436) |
| Total adjustments | 1,806 | (35,245) |
| Net cash used in operating activities | (3,377) | (4,416) |
| **Cash flows from investing activities** | | |
| Purchases of property and equipment | (26) | (18) |
| Purchases of available-for-sale securities | (5,382) | (7,021) |
| Proceeds from maturities of available-for-sale securities | 5,840 | 10,098 |
| Net cash provided by investing activities | 432 | 3,059 |
| **Cash flows from financing activities** | | |
| Payments on equipment financing obligations | (2) | (2) |
| Net proceeds from issuances of common stock | 2 | |
| Net cash used in financing activities | | (2) |
| Net decrease in cash and cash equivalents | (2,945) | (1,359) |
| Cash and cash equivalents, beginning of the period | 11,195 | 8,896 |
| Cash and cash equivalents, end of the period | $ 8,250 | $ 7,537 |

The accompanying notes are an integral part of these financial statements.

Table of Contents

**DURECT CORPORATION**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**Note 1. Summary of Significant Accounting Policies**

***Nature of Operations***

DURECT Corporation (the Company) was incorporated in the state of Delaware on February 6, 1998. The Company is a pharmaceutical company developing therapies based on its proprietary drug formulations and delivery platform technologies. The Company has several products under development by itself and with third party collaborators. The Company also manufactures and sells osmotic pumps used in laboratory research, and designs, develops and manufactures a wide range of standard and custom biodegradable polymers and excipients for pharmaceutical and medical device clients for use as raw materials in their products. In addition, the Company conducts research and development of pharmaceutical products in collaboration with third party pharmaceutical and biotechnology companies.

***Basis of Presentation***

The accompanying unaudited financial statements include the accounts of the Company. These financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and therefore, do not include all the information and footnotes necessary for a complete presentation of the Company s results of operations, financial position and cash flows in conformity with U.S. generally accepted accounting principles (U.S. GAAP). The unaudited financial statements reflect all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair presentation of the financial position at March 31, 2013, the operating results for the three months ended March 31, 2013 and 2012, and cash flows for the three months ended March 31, 2013 and 2012. The balance sheet as of December 31, 2012 has been derived from audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These financial statements and notes should be read in conjunction with the Company s audited financial statements and notes thereto, included in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2012 filed with the SEC.

The results of operations for the interim periods presented are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year.

***Inventories***

Inventories are stated at the lower of cost or market, with cost determined on a first-in, first-out basis. The Company s inventories consisted of the following (in thousands):

| | March 31, 2013 | December 31, 2012 |
|---|---|---|
| Raw materials | $ 1,103 | $ 1,149 |
| Work in process | 925 | 1,011 |
| Finished goods | 1,030 | 1,239 |
| Total inventories | $ 3,058 | $ 3,399 |

***Revenue Recognition***

Revenue from the sale of products is recognized when there is persuasive evidence that an arrangement exists, the product is shipped and title transfers to customers, provided no continuing obligation on the Company s part exists, the price is fixed or determinable and the collectability of the amounts owed is reasonably assured. The Company enters into license and collaboration agreements under which it may receive upfront license fees, research funding and contingent milestone payments and royalties. The Company s deliverables under these arrangements typically consist of granting licenses to intellectual property rights and providing research and development services. The accounting standards contain a presumption that separate contracts entered into at or near the same time with the same entity or related parties were negotiated as a package and should be evaluated as a single agreement.

Revenue on cost-plus-fee contracts, such as under contracts to perform research and development for others, is recognized as the related services are rendered as determined by the extent of reimbursable costs incurred plus estimated fees thereon.

***Comprehensive Income (Loss)***

Components of other comprehensive income (loss) are comprised entirely of unrealized gains and losses on the Company s available-for-sale securities for all periods presented and are included in total comprehensive income (loss) as follows (in thousands).

Table of Contents

| | Three months ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Net income (loss) | $ (5,183) | $ 30,829 |
| Net change in unrealized gain (loss) on available-for-sale investments | 2 | (3) |
| Comprehensive income (loss) | $ (5,181) | $ 30,826 |

The tax effect of the changes in accumulated other comprehensive income was immaterial for the periods presented. Accumulated other comprehensive income as of March 31, 2013 and December 31, 2012 is entirely comprised of net unrealized gains and losses on available-for-sale securities.

***Net Income (Loss) Per Share***

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding. Diluted net income (loss) per share is computed using the weighted-average number of common shares outstanding and common stock equivalents (i.e., options and warrants to purchase common stock) outstanding during the period, if dilutive, using the treasury stock method for options and warrants.

The numerators and denominators in the calculation of basic and diluted net income (loss) per share were as follows (in thousands except per share amounts):

| | Three months ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Numerators: | | |
| Net income (loss) | $ (5,183) | $ 30,829 |
| Denominators: | | |
| Outstanding dilutive securities not included in diluted net loss per share | | |
| Weighted average shares used to compute basic net income (loss) per share | 101,881 | 87,547 |
| Effect of dilutive securities: | | |
| Dilution from stock options | | 21 |
| Dilutive common shares | | 21 |
| Weighted average shares used to compute basic net income (loss) per share | 101,881 | 87,568 |
| Net income (loss) per share: | | |
| Basic | $ (0.05) | $ 0.35 |
| Diluted | $ (0.05) | $ 0.35 |

Options to purchase approximately 21.0 million and 21.3 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the three months ended March 31, 2013 and 2012, respectively, as the effect would be anti-dilutive.

Table of Contents

**Note 2. Strategic Agreements**

The collaborative research and development and other revenues associated with the Company s major third-party collaborators are as follows (in thousands):

| | Three months ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| **Collaborator** | | |
| Zogenix, Inc. (Zogenix) (1) | $ 253 | $ 1,284 |
| Pfizer Inc. (Pfizer) (2) | 13 | 10,388 |
| Pain Therapeutics, Inc. (Pain Therapeutics) | | 1 |
| Hospira, Inc. (Hospira) (3) | | 22,774 |
| Nycomed Danmark, APS (Nycomed) (4) | | 3,705 |
| Others | 647 | 176 |
| Total collaborative research and development and other revenue | $ 913 | $ 38,328 |

(1) Amounts related to the ratable recognition of upfront fees were $50,000 and $78,000 for the three months ended March 31, 2013 and 2012, respectively.

(2) Amounts related to the recognition of upfront fees were zero and $9.9 million for the three months ended March 31, 2013 and 2012, respectively. In February 2011, Pfizer acquired King Pharmaceuticals (King) and thereby assumed the rights and obligations of King under the agreements we formerly had in place with King; accordingly amounts attributed to King are now shown as Pfizer figures. In February 2012, the Company was notified that Pfizer was terminating the worldwide Development and License Agreement between Alpharma (acquired by King which subsequently was acquired by Pfizer) and DURECT dated September 19, 2008 relating to the development and commercialization of ELADUR. As a result, the Company recognized as revenue all of the remaining upfront fees during the three months ended March 31, 2012 that had previously been deferred.

(3) Amounts related to the recognition of upfront fees were zero and $21.8 million for the three months ended March 31, 2013 and 2012, respectively. In March 2012, the Company was notified that Hospira was terminating the Development and License Agreement between Hospira and the Company dated June 1, 2010 relating to the development and commercialization of POSIDUR in the United States and Canada. As a result, the Company recognized as revenue all of the remaining upfront fees during the three months ended March 31, 2012 that had previously been deferred.

(4) Amounts related to the ratable recognition of upfront fees were zero and $3.7 million for the three months ended March 31, 2013 and 2012, respectively. In January 2012, the Company that was notified Nycomed was terminating the Development and License Agreement between Nycomed and the Company dated November 26, 2006, as amended relating to the development and commercialization of POSIDUR (SABER-Bupivacaine) in Europe and their other licensed territories. As a result, the Company recognized as revenue all of the remaining upfront fees during the three months ended March 31, 2012 that had previously been deferred.

***Agreement with Pain Therapeutics, Inc.***

In December 2002, the Company entered into an exclusive agreement with Pain Therapeutics, Inc. (Pain Therapeutics) to develop and commercialize on a worldwide basis REMOXY and other oral sustained release, abuse deterrent opioid products incorporating four specified opioid drugs, using the ORADUR technology. Total collaborative research and development revenue recognized under the agreements with Pain Therapeutics was zero and $1,000 for the three months ended March 31, 2013 and 2012, respectively. The cumulative aggregate payments received by the Company from Pain Therapeutics as of March 31, 2013 were $34.2 million under this agreement.

Under the terms of this agreement, Pain Therapeutics paid the Company an upfront license fee of $1.0 million, with the potential for an additional $9.3 million in performance milestone payments based on the successful development and approval of the four ORADUR-based opioids. Of these potential milestones, $9.3 million are development-based milestones (of which $1.7 million had been achieved as of March 31, 2013). There are no sales-based milestones under the agreement.

In March 2009, King assumed the responsibility for further development of REMOXY from Pain Therapeutics. As a result of this change, the Company continues to perform REMOXY-related activities in accordance with the terms and conditions set forth in the license agreement

between the Company and Pain Therapeutics. Accordingly, King was substituted in lieu of Pain Therapeutics with respect to interactions with the Company in its performance of those activities including the obligation to pay the Company with respect to all REMOXY-related costs incurred by the Company. In February 2011, Pfizer acquired King and thereby assumed the rights and obligations of King with respect to REMOXY; accordingly amounts attributed to King are now shown as Pfizer figures.

Table of Contents

Total collaborative research and development revenue recognized for REMOXY-related work performed by the Company for Pfizer was $13,000 and $471,000 for the three months ended March 31, 2013 and 2012, respectively. Prior to March 2009, the Company recognized collaborative research and development revenue for REMOXY-related work under the agreements with Pain Therapeutics. The cumulative aggregate payments received by the Company from Pfizer and King as of March 31, 2013 were $7.0 million under this agreement.

***Long Term Supply Agreement with King (now Pfizer)***

In August 2009, the Company signed an exclusive long term excipient supply agreement with respect to REMOXY with King (now Pfizer). This agreement stipulates the terms and conditions under which the Company will supply to King, based on the Company s manufacturing cost plus a specified percentage mark-up, two key excipients used in the manufacture of REMOXY. In February 2011, Pfizer acquired King and thereby assumed the rights and obligations of King under the agreements we formerly had in place with King; accordingly amounts attributed to King are now shown as Pfizer figures.

In the three months ended March 31, 2013 and 2012, the Company recognized $273,000 and $51,000 of product revenue related to a key excipient for REMOXY. The associated costs of goods sold were $219,000 and $33,000 in the three months ended March 31, 2013 and 2012.

***Agreement with Zogenix, Inc.***

On July 11, 2011, the Company and Zogenix, Inc., (Zogenix), entered into a Development and License Agreement (the License Agreement). The Company and Zogenix had previously been working together under a feasibility agreement pursuant to which the Company s research and development costs were reimbursed by Zogenix. Under the License Agreement, Zogenix will be responsible for the clinical development and commercialization of a proprietary, long-acting injectable formulation of risperidone using the Company s SABER controlled-release formulation technology in combination with Zogenix s DosePro® needle-free, subcutaneous drug delivery system. DURECT will be responsible for non-clinical, formulation and CMC development activities. The Company will be reimbursed by Zogenix for its research and development efforts on the product.

Zogenix paid a non-refundable upfront fee to the Company of $2.25 million in July 2011. The Company s research and development services are considered integral to utilizing the licensed intellectual property and, accordingly, the deliverables are accounted for as a single unit of accounting. The $2.25 million upfront fee is being recognized as collaborative research and development revenue ratably over the term of the Company s continuing research and development involvement with Zogenix with respect to this product candidate. Zogenix is obligated to pay the Company up to $103 million in total future milestone payments with respect to the product subject to and upon the achievement of various development, regulatory and sales milestones. Of these potential milestones, $28 million are development-based milestones (none of which had been achieved as of March 31, 2013), and $75 million are sales-based milestones (none of which had been achieved as of March 31, 2013). Zogenix is also required to pay a mid single-digit to low double-digit percentage patent royalty on annual net sales of the product determined on a jurisdiction-by-jurisdiction basis. The patent royalty term is equal to the later of the expiration of all DURECT technology patents or joint patent rights in a particular jurisdiction, the expiration of marketing exclusivity rights in such jurisdiction, or 15 years from first commercial sale in such jurisdiction. After the patent royalty term, Zogenix will continue to pay royalties on annual net sales of the product at a reduced rate for so long as Zogenix continues to sell the product in the jurisdiction. Zogenix is also required to pay to the Company a tiered percentage of fees received in connection with any sublicense of the licensed rights.

The Company granted to Zogenix an exclusive worldwide license, with sub-license rights, to the Company s intellectual property rights related to the Company s proprietary polymeric and non-polymeric controlled-release formulation technology to make and have made, use, offer for sale, sell and import risperidone products, where risperidone is the sole active agent, for administration by injection in the treatment of schizophrenia, bipolar disorder or other psychiatric related disorders in humans. The Company retains the right to supply Zogenix s Phase 3 clinical trial and commercial product requirements on the terms set forth in the License Agreement.

The Company retains the right to terminate the License Agreement with respect to specific countries if Zogenix fails to advance the development of the product in such country, either directly or through a sublicensee. In addition, either party may terminate the License Agreement upon insolvency or bankruptcy of the other party, upon written notice of a material uncured breach or if the other party takes any act impairing such other party s relevant intellectual property rights. Zogenix may terminate the License Agreement upon written notice if during the development or commercialization of the product, the product becomes subject to one or more serious adverse drug experiences or if either party receives notice from a regulatory authority, independent review committee, data safety monitory board or other similar body alleging significant concern regarding a patient safety issue. Zogenix may also terminate the License Agreement with or without cause, at any time upon prior written notice.

9

Table of Contents

The following table provides a summary of collaborative research and development revenue recognized under the agreements with Zogenix (in thousands). The cumulative aggregate payments received by the Company as of March 31, 2013 were $10.3 million under these agreements.

| | Three months ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Ratable recognition of upfront payment | $ 50 | $ 78 |
| Research and development expenses reimbursable by Zogenix | 203 | 1,206 |
| Total collaborative research and development revenue | $ 253 | $ 1,284 |

**Note 3. Financial Instruments**

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 Company s valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The Company follows a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value. These levels of inputs are the following:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company s financial instruments are valued using quoted prices in active markets or based upon other observable inputs. Money market funds are classified as Level 1 financial assets. Certificates of deposit, commercial paper, corporate debt securities, and U.S. Government agency securities are classified as Level 2 financial assets. The fair value of the Level 2 assets is estimated using pricing models using current observable market information for similar securities. The Company s Level 2 investments include U.S. government-backed securities and corporate securities that are valued based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. The fair value of the Company s commercial paper is based upon the time to maturity and discounted using the three-month treasury bill rate. The average remaining maturity of the Company s Level 2 investments as of March 31, 2013 is less than twelve months and these investments are rated by S&P and Moody s at AAA or AA- for securities and A1 or P1 for commercial paper.

**Table of Contents**

The following is a summary of available-for-sale securities as of March 31, 2013 and December 31, 2012 (in thousands):

| | March 31, 2013 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gain | Unrealized Loss | Estimated Fair Value |
| Money market funds | $ 4,789 | $ | $ | $ 4,789 |
| Certificates of deposit | 300 | | | 300 |
| Commercial paper | 3,199 | | | 3,199 |
| Corporate debt | 3,413 | 2 | | 3,415 |
| U.S. Government agencies | 11,160 | 3 | (1) | 11,162 |
| | $ 22,861 | $ 5 | $ (1) | $ 22,865 |
| Reported as: | | | | |
| Cash and cash equivalents | $ 5,588 | $ | $ | $ 5,588 |
| Short-term investments | 16,257 | 5 | (1) | 16,261 |
| Long-term investments | 716 | | | 716 |
| Long-term restricted investments | 300 | | | 300 |
| | $ 22,861 | $ 5 | $ (1) | $ 22,865 |

| | December 31, 2012 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gain | Unrealized Loss | Estimated Fair Value |
| Money market funds | $ 4,204 | $ | $ | $ 4,204 |
| Certificates of deposit | 550 | | | 550 |
| Commercial paper | 8,993 | | | 8,993 |
| Corporate debt | 3,806 | 1 | | 3,807 |
| U.S. Government agencies | 10,045 | 5 | | 10,050 |
| | $ 27,598 | $ 6 | $ | $ 27,604 |
| Reported as: | | | | |
| Cash and cash equivalents | $ 9,867 | $ | $ | $ 9,867 |
| Short-term investments | 17,331 | 6 | | 17,337 |
| Long-term restricted investments | 400 | | | 400 |
| | $ 27,598 | $ 6 | $ | $ 27,604 |

The following is a summary of the cost and estimated fair value of available-for-sale securities at March 31, 2013, by contractual maturity (in thousands):

| | March 31, 2013 | |
|---|---|---|
| | Amortized Cost | Estimated Fair Value |
| Mature in one year or less | $ 17,356 | $ 17,360 |

| | | |
|---|---|---|
| Mature after one year through five years | 716 | 716 |
| | $ 18,072 | $ 18,076 |

There were no securities that have had an unrealized loss for more than 12 months as of March 31, 2013.

As of March 31, 2013, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered to be temporary. The Company believes that it is more-likely-than-not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value.

Table of Contents

**Note 4. Stock-Based Compensation**

As of March 31, 2013, the Company has three stock-based employee compensation plans. The employee stock-based compensation cost that has been included in the statements of comprehensive income (loss) is shown as below (in thousands):

| | Three months ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Cost of product revenues | $ 49 | $ 64 |
| Research and development | 570 | 698 |
| Selling, general and administrative | 326 | 414 |
| Total stock-based compensation | $ 945 | $ 1,176 |

As of March 31, 2013 and December 31, 2012, $19,000 and $23,000, respectively, of stock-based compensation cost was capitalized in inventory on the Company s balance sheets.

The Company uses the Black-Scholes option pricing model to value its stock options. The expected life computation is based on historical exercise patterns and post-vesting termination behavior. The Company considered its historical volatility in developing its estimate of expected volatility.

The Company used the following assumptions to estimate the fair value of options granted and shares purchased under its employee stock purchase plan for the three months ended March 31, 2013 and 2012:

| | Stock Options Three months ended March 31, | | Employee Stock Purchase Plan Three months ended March 31, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| Risk-free rate | 0.77-1.54% | 1.1-1.5% | 0.15% | 0.1-0.2% |
| Expected dividend yield | | | | |
| Expected life of option (in years) | 5.25-7.75 | 6.50 | 1.25 | 1.25 |
| Volatility | 77-86% | 78-79% | 69% | 50-163% |
| Forfeiture rate | 8.4% | 7.7% | | |

Table of Contents

**Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations**

This Management s Discussion and Analysis of Financial Condition and Results of Operations for the three months ended March 31, 2013 and 2012 should be read in conjunction with our annual report on Form 10-K for the year ended December 31, 2012 filed with the Securities and Exchange Commission and Risk Factors section included elsewhere in this Form 10-Q. This Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. When used in this report, the words believe, anticipate, intend, plan, estimate, expect, may, will, could, potentially expressions are forward-looking statements. Such forward-looking statements are based on current expectations and beliefs. Any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors.

*Forward-looking statements made in this report include, for example, statements about:*

potential regulatory filings for or approval of REMOXY, POSIDUR or any of our other product candidates;

the progress of our third-party collaborations, including estimated milestones;

our intention to seek, and ability to enter into strategic alliances and collaborations;

the potential benefits and uses of our products;

responsibilities of our collaborators, including the responsibility to make cost reimbursement, milestone, royalty and other payments to us, and our expectations regarding our collaborators plans with respect to our products;

our responsibilities to our collaborators, including our responsibilities to conduct research and development, clinical trials and manufacture products;

our ability to protect intellectual property, including intellectual property licensed to our collaborators;

market opportunities for products in our product pipeline;

the number of patients enrolled and the timing of patient enrollment in clinical trials;

the progress and results of our research and development programs;

requirements for us to purchase supplies and raw materials from third parties, and the ability of third parties to provide us with required supplies and raw materials;

the results and timing of clinical trials and the commencement of future clinical trials;

conditions for obtaining regulatory approval of our product candidates;

submission and timing of applications for regulatory approval;

the impact of FDA, DEA, EMEA and other government regulation on our business;

the impact of potential Risk Evaluation and Mitigation Strategies (REMS) on our business;