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;

uncertainties associated with obtaining and protecting patents and other intellectual property rights, as well as avoiding the intellectual property rights of others;

products and companies that will compete with the products we license to third-party collaborators;

the possibility we may commercialize our own products and build up our commercial, sales and marketing capabilities and other required infrastructure;

the possibility that we may develop additional manufacturing capabilities;

our employees, including the number of employees and the continued services of key management, technical and scientific personnel;

our future performance, including our anticipation that we will not derive meaningful revenues from our pharmaceutical product candidates for at least the next twelve months and our expectations regarding our ability to achieve profitability;

sufficiency of our cash resources, anticipated capital requirements and capital expenditures and our need for additional financing;

our expectations regarding marketing expenses, research and development expenses, and selling, general and administrative expenses;

the composition of future revenues; and

accounting policies and estimates, including revenue recognition policies.

Table of Contents

*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. For a more detailed discussion of such forward looking statements and the potential risks and uncertainties that may impact upon their accuracy, see the Risk Factors section and Overview section of this Management s Discussion and Analysis of Financial Condition and Results of Operations. These forward-looking statements reflect our view only as of the date of this report. We undertake no obligations to update any forward-looking statements. You should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission.*

**Overview**

We are a specialty pharmaceutical company focused on the development of pharmaceutical products based on our proprietary drug delivery technology platforms. Our product pipeline currently consists of eight investigational drug candidates in clinical development, with one program the subject of a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for which a Complete Response Letter was received in June 2011, another program for which we submitted an NDA to the FDA in April 2013, two programs in Phase II and four programs in Phase I. The more advanced programs are in the field of pain management and we believe that each of these targets large market opportunities with product features that are differentiated from existing therapeutics. We have other programs underway in fields outside of pain management, including several efforts underway which seek to improve the administration of biotechnology agents such as proteins and peptides.

A central aspect of our business strategy involves advancing multiple product candidates at one time, which is enabled by leveraging our resources with those of corporate collaborators. Thus, certain of our programs are currently licensed to corporate collaborators on terms which typically call for our collaborator to fund all or a substantial portion of future development costs and then pay us milestone payments based on specific development or commercial achievements plus a royalty on product sales. At the same time, we have retained the rights to other programs, which are the basis of future collaborations and which over time may provide a pathway for us to develop our own commercial, sales and marketing organization.

Additional details of these programs and related strategic agreements are contained in our annual report on Form 10-K for the year ended December 31, 2012 or in Note 2 above.

***REMOXY® and other ORADUR®-based opioid products licensed to Pain Therapeutics***

In December 2002, we entered into an agreement with Pain Therapeutics, amended in December 2005, under which we granted Pain Therapeutics the exclusive, worldwide right to develop and commercialize selected long-acting oral opioid products using our ORADUR technology incorporating four specified opioid drugs. The first product being developed under the collaboration is REMOXY, a novel long-acting oral formulation of the opioid oxycodone targeted to decrease the potential for oxycodone abuse. REMOXY is intended for patients with chronic pain. In November 2005, Pain Therapeutics and King entered into collaboration and license agreements for the development and commercialization of REMOXY by King. In February 2011, Pfizer acquired King and thereby assumed the rights and obligations of King with respect to REMOXY and to the other ORADUR-based opioids.

An NDA was submitted in June 2008 by Pain Therapeutics, in response to which the FDA provided a Complete Response Letter in December 2008. King took over the NDA from Pain Therapeutics and resubmitted the NDA in December of 2010. On June 23, 2011, a Complete Response Letter from the FDA was received by Pfizer on the resubmission to the NDA for REMOXY. The FDA s June 2011 Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. Pfizer has efforts underway to resolve these issues. On April 30, 2013, Pfizer stated that it had a productive meeting regarding REMOXY with the FDA in late March and had received guidance that is helping to inform the next steps in addressing the issues raised by the FDA in the Complete Response Letter. Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the FDA s Complete Response Letter.

Phase I clinical trials have been conducted for two of the other ORADUR-based products (hydrocodone and hydromorphone), and an Investigational New Drug (IND) application has been accepted by the FDA for the fourth ORADUR-based opioid (oxymorphone).

*NOTE: POSIDUR , SABER®, CLOUD ,TRANSDUR®, ORADUR®, ELADUR®, DURIN®, CHRONOGESIC®, MICRODUR , ALZET® and LACTEL® are trademarks of DURECT Corporation. Other trademarks referred to belong to their respective owners.*

14

Table of Contents

***POSIDUR (SABER®-Bupivacaine)***

Our post-operative pain relief depot, POSIDUR, is a sustained release injectable using our SABER delivery system to deliver bupivacaine, an off-patent anesthetic agent. SABER is a patented controlled drug delivery technology that is administered via the parenteral (i.e., injectable) route to deliver drugs that act systemically or locally. POSIDUR is designed to be administered to a surgical site at the time of surgery for post-operative pain relief and is intended to provide local analgesia for up to 3 days, which we believe coincides with the time period of the greatest need for post-surgical pain control in most patients.

In November 2006, we entered into a development and license agreement with Nycomed (amended in February 2010 and February 2011) under which we licensed to Nycomed the exclusive commercialization rights to POSIDUR for the European Union (E.U.) and certain other countries. In June 2010, we entered into a development and license agreement with Hospira to develop POSIDUR for the U.S. and Canada and under which we licensed to Hospira exclusive commercialization rights in the U.S. and Canada. In October 2011, Takeda Pharmaceutical Company Limited (Takeda) acquired Nycomed and thereby assumed the rights and obligations of Nycomed under the agreements the Company formerly had in place with Nycomed. In January 2012, Takeda (through Nycomed) notified us that it was terminating the license agreement with us, and thereby returning their right to develop and commercialize POSIDUR in Europe and their other licensed territories to us. In March 2012, Hospira notified us that it was terminating the license agreement with us, and thereby returning their right to develop and commercialize POSIDUR in the U.S. and Canada to us by September 28, 2012, or an earlier date at our election. We have initiated discussions with other potential partners regarding licensing development and commercialization rights to this program to which we hold worldwide rights.

In July 2012, we completed pre-NDA communications with the FDA regarding POSIDUR. Through this process, we received guidance and thoughtful comments from the FDA covering various chemistry, manufacturing, non-clinical, clinical pharmacology, clinical, statistical and product labeling topics. In April 2013, with the input we have received from the FDA and leveraging off the well established history of bupivacaine use, we submitted an NDA as a 505(b)(2) application, which relies in part on the FDA s findings of safety and effectiveness of a reference drug. We expect that the FDA will notify us whether our NDA submission has been accepted for filing in June 2013. If accepted for filing, the FDA would be expected to assign a Prescription Drug User Fee Act (PDUFA) target date (the date the FDA expects to complete its review of the POSIDUR NDA) in the first quarter of 2014.

*Safety*

As bupivacaine is a well known drug with an extensive understanding of its risks and benefits, the safety database in the Integrated Summary of Safety (ISS) is not as large as required for a new chemical entity. A total of 1075 patients are included in the ISS database, 951 of whom have been exposed to POSIDUR or SABER-Placebo in volumes ranging from 2.5 to 10 mL. A total of 683 patients have been exposed to POSIDUR with the dose of bupivacaine ranging from 330 to 990 mg. In addition, a total of 124 patients have been treated with bupivacaine HCl in control groups and 268 patients received SABER-Placebo in control groups.

Overall, the POSIDUR patient groups showed a similar systemic safety profile as the patient groups treated with SABER-Placebo and bupivacaine HCl. Long-term follow-up examinations over 6 to 18 months do not show any adverse effects on wound healing or scar formation from the use of POSIDUR or SABER-Placebo. Local site reactions were observed more frequently in the POSIDUR and SABER-Placebo groups than in the active comparator groups, most frequently in abdominal surgeries; most of these observations were discolorations (e.g., surgical bruising), the majority of which resolved without treatment during the observation period. There was little difference in the incidence of severe or serious adverse events between the POSIDUR, SABER-Placebo and bupivacaine HCl treatment groups. Most of the serious adverse events seen in these trials appear to be due to complications of surgery, anesthesia, analgesics, or co-morbidity and not POSIDUR-related. The clinical history for serious adverse events has been reviewed and no evidence of bupivacaine toxicity was apparent. The adverse event data have been analyzed in a variety of ways to detect any evidence of bupivacaine central nervous system or cardiac toxicity or other unexpected effects. No patients treated with POSIDUR had an instance of a severe central nervous system or cardiac adverse event traditionally associated with bupivacaine toxicity.

*Efficacy*

In the NDA, we have presented the results from two efficacy trials that we are positioning as pivotal (inguinal hernia repair and shoulder surgery, primarily subacromial decompression) and an Integrated Summary of Efficacy (ISE) based on 7 randomized, controlled, parallel design surgical trials of POSIDUR using the administration technique and 5 mL (660 mg) dose proposed for marketing.

*Hernia pivotal efficacy trial*

The hernia pivotal efficacy clinical trial was designed to evaluate the tolerability, activity, dose response and pharmacokinetics of POSIDUR in patients undergoing open inguinal hernia repair. The trial was conducted in Australia and New Zealand as a multi-center, randomized, double blind, placebo-controlled study in 122 patients. Study patients were randomized into three treatment

Table of Contents

groups: patients that were treated with POSIDUR 2.5 mL (n=43), POSIDUR 5 mL (n=47) and placebo (n=32). The co-primary efficacy endpoints for the study were Mean Pain Intensity on Movement area under the curve (AUC), a measure of pain over a period of 1-72 hours post-surgery, and the proportion of patients requiring supplemental opioid analgesic medication during the study (defined as 0-15 days).

In relation to the co-primary endpoint of pain reduction as measured by Mean Pain Intensity on Movement AUC 1-72 hours post-surgery, the patient group treated with POSIDUR 5 mL reported thirty-one percent (31%) less pain versus placebo and was statistically significant (p=0.0033). Fifty-three percent (53%) of the study patients in the POSIDUR 5 mL group took supplemental opioid analgesic medications versus seventy-two percent (72%) of the placebo patients (p=0.0909). Although this positive trend for this co-primary endpoint in favor of the POSIDUR 5 mL group was not statistically significant, both secondary endpoints measuring opioid analgesic medication consumption were met at a statistically significant level. During the periods of 1-24 hours, 24-48 hours and 48-72 hours after surgery, placebo patients consumed approximately 3.5 (p=0.0009), 2.9 (p=0.0190) and 3.6 (p=0.0172) times more supplemental opioid analgesic medications (mean total daily consumption of opioid analgesic medication in morphine equivalents), respectively, than the POSIDUR 5 mL treatment group. The median decrease in supplemental opioid analgesics taken over the first three days after surgery was 80% (p=0.0085) for the POSIDUR 5mL group as compared to the placebo group.

*Shoulder pivotal efficacy trial*

The shoulder pivotal efficacy trial was a multicenter, randomized, double-blind, active- and placebo-controlled, parallel-group, dose-response trial conducted at 9 investigational centers in Europe. Nycomed, DURECT s collaborator at the time, was responsible for the conduct of the clinical trial. In this study, 107 patients were randomly assigned to one of three treatment groups prior to undergoing elective arthroscopic shoulder surgery: POSIDUR 5 mL (n=53), SABER-Placebo (n=25) or bupivacaine HCl solution (n=29). All patients were given a background pain treatment consisting of a daily dose of two or four grams (depending on the patient s weight) of paracetamol (acetaminophen). In addition, each patient was provided supplemental opioid rescue medication, if needed. With respect to efficacy, the primary endpoints of the study were to demonstrate: (1) an improvement in terms of pain intensity on movement area under the curve (AUC) during the period 1 72 hours post-surgery, and (2) a decrease in the total use of opioid rescue analgesia 0 72 hours post-surgery.

Results from this study demonstrate that the POSIDUR group experienced a statistically significant reduction in pain intensity of approximately 21% (p=0.0122) versus SABER-Placebo. Applying the appropriate statistical test given the data distribution, the POSIDUR group showed a statistically significant reduction of approximately 67% (p=0.013) in median opioid use in favor of POSIDUR. No statistical differences were found when POSIDUR was compared to bupivacaine HCl.

*Phase III trial in abdominal surgical procedures*

We also conducted a Phase III U.S. and international, multi-center, randomized, double-blind, controlled trial evaluating the safety, efficacy, effectiveness, and pharmacokinetics of POSIDUR in 305 patients undergoing a variety of general abdominal surgical procedures. The trial included the following three cohorts:

Cohort 1: An active comparator cohort in which patients were randomized to receive either POSIDUR 5 mL or commercially available Bupivacaine HCl solution after laparotomy.

Cohort 2: An active comparator cohort in which patients were randomized to receive either POSIDUR 5 mL or commercially available Bupivacaine HCl solution after laparoscopic cholecystectomy.

Cohort 3: A double blind, placebo controlled cohort in which patients were randomized to receive either POSIDUR 5 mL or SABER-Placebo after laparoscopically-assisted colectomy.

Efficacy evaluation in the Phase III trial encompassed a number of parameters. The two co-primary efficacy endpoints for Cohort 3 were mean pain intensity on movement (normalized) Area Under the Curve (AUC) during the period 0-72 hours post-dose and mean total morphine equivalent opioid dose for supplemental analgesia during the period 0-72 hours post-dose. The purpose of Cohorts 1 and 2 was to give us additional experience with the use of POSIDUR in a broader group of surgeries and patients.

Cohort 3. With respect to the co-primary efficacy endpoint of pain reduction as measured by mean pain intensity on movement (normalized) Area Under the Curve (AUC) during the period 0-72 hours post-dose, the patient group treated with POSIDUR reported a mean pain reduction in pain scores of approximately 7%, although this was not statistically significant (p=0.1466). The statistical analysis plan included pain on movement as recorded at scheduled times through an electronic diary plus pain scores reported whenever supplemental opioids were administered with such scores attributed as if they were pain on movement. In the prespecified sensitivity analysis (which includes only

scheduled pain assessment on movement scores as collected on the electronic diary), the patient group treated with POSIDUR reported approximately 10% less pain versus placebo (p=0.0410). In relation to the co-primary efficacy endpoint of median total morphine-equivalent opioid dose for supplemental analgesia during the period 0-72 hours post-dose, the patient group treated with POSIDUR reported approximately 16% less opioids consumed versus the placebo group, although this was not statistically significant (p=0.5897).

Table of Contents

Cohorts 1 and 2. Cohorts 1 and 2 were prespecified to be pooled due to their small sample size. For Cohorts 1 and 2 (pooled), the mean reduction in pain on movement was approximately 20% and statistically significant (p=0.0111) for the POSIDUR group compared to the patient group treated with bupivacaine HCl. The median total morphine-equivalent opioid dose for supplemental analgesia during the period 0-72 hours post-dose for Cohorts 1 and 2 (pooled), the patient group treated with POSIDUR reported approximately 18% less opioids consumed compared to the bupivacaine HCl group, although this was not statistically significant (p=0.5455).

*Integrated Summary of Efficacy*

The seven controlled trials in the ISE can be separated into two basically different surgical types. The four soft tissue trials involved incisions or laparoscopic portals either in the abdomen or in the inguinal area for hernia repair. In these surgeries, the pain producing tissue was primarily soft tissue such as viscera, fascia, muscle, or skin. However, in the three orthopedic surgeries involving shoulder surgery, a major pain producing tissue is bone that has been resected during the procedure. Given that the responsiveness to treatment of these different surgical types may be different, a pooled analysis has been conducted separated by tissue type.

In the soft tissue pooled analysis group comprised of 410 patients, 253 were treated with POSIDUR and 157 were treated with SABER-Placebo. The mean pain intensity was lower during the period 0-72 hours post-dose in the POSIDUR group than in the SABER-Placebo group and the difference was statistically significant (p=0.0099). The median total morphine-equivalent dose during the period 0-72 hours post-dose was lower in the POSIDUR group than in the SABER-Placebo group, however the difference was not statistically significant.

In the orthopedic pooled analysis group comprised of 187 patients, 114 were treated with POSIDUR and 73 were treated with SABER-Placebo. The mean pain intensity during the period 0-72 hours post-dose was lower in the POSIDUR group than in the SABER-Placebo group and the difference was statistically significant (p=0.0205). The median total morphine-equivalent dose during the period 0-72 hours post-dose was lower in the POSIDUR group than in the SABER-Placebo group and the difference was statistically significant (p=0.0025).

***ELADUR ® (TRANSDUR®-Bupivacaine)***

Our transdermal bupivacaine patch (ELADUR) uses our proprietary TRANSDUR transdermal technology and is intended to provide continuous delivery of bupivacaine for up to three days from a single application, as compared to a wearing time limited to 12 hours with currently available lidocaine patches. In December 2007, we announced positive results from a 60 patient Phase IIa study for post-herpetic neuralgia (PHN or post-shingles pain).

Effective in October 2008, we entered into a development and license agreement with Alpharma granting Alpharma the exclusive worldwide rights to develop and commercialize ELADUR. Alpharma paid us an upfront license fee of $20 million in October 2008. Alpharma was acquired by King in December 2008 and, as a result, the rights and obligations of the agreement were assumed by King. In February 2011, Pfizer acquired King and thereby assumed the rights and obligations of King with respect to ELADUR.

We reported top line data from a Phase II clinical trial conducted by King for ELADUR in April 2011. In this study of 263 patients suffering from chronic low back pain, the primary efficacy endpoint of demonstrating a positive treatment difference for the mean change in pain intensity scores from baseline to the mean of weeks 11 and 12 between ELADUR as compared to placebo was not met.

In February 2012, Pfizer gave notice that its rights with respect to ELADUR were being returned to us. We have initiated discussions with other potential partners regarding licensing development and commercialization rights to this program.

***TRANSDUR®-Sufentanil***

Our transdermal sufentanil patch (TRANSDUR-Sufentanil) uses our proprietary TRANSDUR delivery system to deliver sufentanil, an opioid medication. TRANSDUR-Sufentanil is designed to provide extended chronic pain relief for up to seven days, as compared to the two to three days of relief provided with currently available opiate patches. We anticipate that the small size of our sufentanil patch (potentially as small as $1/5^{th}$ the size of currently marketed transdermal fentanyl patches for a therapeutically equivalent dose) may offer improved convenience and compliance for patients. An end-of-Phase II meeting was conducted with the FDA in February 2009 and we have subsequently had discussions with the FDA and regulatory agencies in several major European countries to better understand development requirements for U.S. and European approval. We are in discussions with potential collaborators regarding licensing development and commercialization rights to this program to which we hold worldwide rights.

17

Table of Contents

***ORADUR-ADHD Program***

We are developing a drug candidate (ORADUR-ADHD) based on DURECT s ORADUR Technology for the treatment of ADHD. This drug candidate is intended to provide once-a-day dosing with added tamper-resistant characteristics to address common methods of abuse and misuse of these types of drugs.

In August 2009, we entered into a development and license agreement with Orient Pharma Co., Ltd., a diversified multinational pharmaceutical, healthcare and consumer products company with headquarters in Taiwan, under which we granted to Orient Pharma development and commercialization rights in certain defined Asian and South Pacific countries to ORADUR-ADHD. DURECT retains rights to North America, Europe, Japan and all other countries not specifically licensed to Orient Pharma. Since 2010, we and Orient Pharma have conducted several Phase I clinical trials in this program with multiple formulations. Based on information from these trials, we are continuing to optimize the lead formulations and are planning next steps in our ORADUR-ADHD program.

***Relday (risperidone) Program***

On July 11, 2011, we and Zogenix, Inc. (Zogenix) entered into a development and license agreement for the purpose of developing and commercializing Relday, a proprietary, long-acting injectable formulation of risperidone using our SABER-controlled release formulation technology in combination with Zogenix s DosePro® needle-free, subcutaneous drug delivery system. Risperidone is one of the most widely prescribed medications used to treat the symptoms of schizophrenia and bipolar I disorder in adults and teenagers 13 years of age and older. Under the agreement, we granted Zogenix worldwide development and commercialization rights to Relday.

On January 3, 2013, Zogenix reported positive single-dose pharmacokinetic (PK) results from the Phase 1 clinical trial of Relday. According to Zogenix, adverse events in the Phase 1 trial in patients diagnosed with schizophrenia were generally mild to moderate and consistent with other risperidone products. The Phase 1 clinical trial for Relday was conducted as a single-center, open-label, safety and PK trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. Per Zogenix, based on the favorable safety and PK profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, Zogenix extended the study to include a 100 mg dose of the same formulation. In May 2013, Zogenix announced positive results with the 100 mg arm, demonstrating dose proportionality across the full dose range that would be anticipated to be used in clinical practice. Zogenix also stated that it has initiated efforts to secure a development and commercialization partner for Relday.

***Other Programs***

*Depot Injectable Programs*

The proteins, peptides and genes identified by the biotechnology industry are large, complex, intricate molecules, and many are unsuitable as drugs. If these molecules are given orally, they are often destroyed before they can have an effect; if given by injection, they often require impractical, inconvenient frequent injections that may result in unwanted side effects. As a result, the development of biotechnology molecules for the treatment of human diseases has room for improvement, and advanced depot injectable systems such as we possess are required to realize the full potential of many of these protein and peptide drugs. In addition to biologic drugs, many traditional small molecule drugs have to be given by frequent injections, which is costly, inconvenient and may result in either unwanted side effects or suboptimal efficacy. We have active programs underway to improve our depot injectable systems and to apply those systems to various drugs and drug candidates, and have entered into a number of feasibility studies with biotechnology and pharmaceutical companies to test their products in our systems.

*Research and Development Programs in Other Therapeutic Categories*

We have underway a number of research programs covering medical diseases and conditions other than pain. Such programs include various diseases and disorders of the central nervous system, cardiovascular disease and metabolic disease. In conducting our research programs and determining which particular efforts to prioritize for formal development, we employ a rigorous opportunity assessment process that takes into account the unmet medical need, commercial opportunity, technical feasibility, clinical viability, intellectual property considerations, and the development path including costs to achieve various critical milestones.

***Product Revenues***

We also currently generate product revenue from the sale of three product lines:

ALZET® osmotic pumps for animal research use;

LACTEL® biodegradable polymers which are used by our customers as raw materials in their pharmaceutical and medical products; and

certain key excipients that are included in REMOXY.

Because we consider our core business to be developing and commercializing pharmaceuticals, we do not intend to significantly increase our investments in or efforts to sell or market any of our existing product lines. However, we expect that we will continue to make efforts to increase our revenue related to collaborative research and development by entering into additional research and development agreements with third-party collaborators to develop product candidates based on our drug delivery technologies.

Table of Contents

***Operating Results***

Since our inception in 1998, we have had a history of operating losses. At March 31, 2013, we had an accumulated deficit of $344.5 million. While we did generate net income of $16.2 million for the year ended December 31, 2012 related to the termination of certain of our collaboration agreements, we have incurred operating losses in other years. Our net losses were $18.8 million and $22.9 million for the years ended December 31, 2011 and 2010, respectively. These losses have resulted primarily from costs incurred to research and develop our product candidates and to a lesser extent, from selling, general and administrative costs associated with our operations and product sales. We expect our research and development expenses to decrease modestly in the near future compared to recent quarters. We also expect selling, general and administrative expenses to remain comparable in the near future. We do not anticipate meaningful revenues from our pharmaceutical product candidates, should they be approved, for at least the next twelve months. Therefore, we expect to incur continuing losses and negative cash flow from operations for the foreseeable future.

**Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. The most significant estimates and assumptions relate to revenue recognition, the recoverability of our long-lived assets, including goodwill and other intangible assets, accrued liabilities, contract research liabilities, inventories and stock-based compensation. Actual amounts could differ significantly from these estimates. There have been no material changes to our critical accounting policies and estimates as compared to the disclosures in our annual report on Form 10-K for the year ended December 31, 2012.

***Results of Operations***

*Three months ended March 31, 2013 and 2012*

*Collaborative research and development and other revenue*

We recognize revenues from collaborative research and development activities and service contracts. Collaborative research and development revenue primarily represents net reimbursement of qualified expenses related to the collaborative agreements with various third parties to research, develop and commercialize potential products using our drug delivery technologies, revenue recognized from ratable recognition of upfront fees and milestone payments in connection with our collaborative agreements.

We expect our collaborative research and development revenue in the next few quarters to be roughly comparable to the first quarter of 2013, pending establishment of new collaborations or an increase in activities undertaken by us under existing collaborations. In general, we expect our collaborative research and development revenue to fluctuate in future periods pending our efforts to enter into potential new collaborations and our existing third party collaborators commitment to and progress in the research and development programs as well as our role in the workplans for those programs at any point in time. The collaborative research and development and other revenues associated with our major 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

Table of Contents

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.

We recorded $913,000 and $38.3 million of collaborative research and development revenue for the three months ended March 31, 2013 and 2012, respectively. The decrease in collaborative research and development revenue in the three months ended March 31, 2013 was primarily attributable to revenue of $35.4 million recognized as a result of the termination of our agreements with Nycomed (with respect to POSIDUR), Pfizer (with respect to ELADUR) and Hospira (with respect to POSIDUR) in the first quarter of 2012; the termination of the agreements and the related recognition of deferred revenue did not reflect in additional cash proceeds to us in the first quarter of 2012. Excluding the impact of recognition of the upfront fees from our agreements with collaborative partners in the three months ended March 31, 2013 and 2012, collaborative research and development revenue decreased by $2.1 million in the three months ended March 31, 2013 due to lower revenue recognized from our agreement with Zogenix as our role in the development activities for Relday decreased in the first quarter of 2013 and lower revenue from our agreements Hospira and Pfizer due to terminated agreements with respect to POSIDUR and ELADUR, partially offset by higher collaborative research and development revenue recognized in connection with our agreements with other feasibility partners compared with the corresponding period in 2012.

We received a $27.5 million upfront fee in connection with the development and license agreement signed with Hospira in June 2010 relating to POSIDUR. The $27.5 million upfront fee had been recognized as collaborative research and development revenue ratably over the term of our continuing involvement with Hospira with respect to POSIDUR. Our estimate of the remaining term of our continuing involvement was revised in the first quarter of 2012 as a result of Hospira s termination notice received by us in March 2012. At March 31, 2012, all of the $27.5 million upfront fee had been recognized as revenue.

We also received a $20.0 million upfront fee in connection with the development and license agreement signed with Alpharma (acquired by King which was subsequently acquired by Pfizer) in September 2008 relating to ELADUR. The $20.0 million upfront fee had been recognized as collaborative research and development revenue ratably over the term of our continuing involvement with Alpharma with respect to ELADUR. Our estimate of the remaining term of our continuing involvement was revised in the first quarter of 2012 as a result of Pfizer s termination notice received by us in February 2012. At March 31, 2012, all of the $20.0 million upfront fee had been recognized as revenue.

We also received a $14.0 million upfront fee in connection with the development and license agreement signed with Nycomed in November 2006 relating to POSIDUR. The $14.0 million upfront fee had been recognized as collaborative research and development revenue ratably over the term of our continuing involvement with Nycomed with respect to POSIDUR. Our estimate of the remaining term of our continuing involvement was revised in the first quarter of 2012 as a result of Nycomed s termination notice received by us in January 2012. At March 31, 2012, all of the $14.0 million upfront fee had been recognized as revenue.

*Product revenue*

A portion of our revenues is derived from product sales, which include our ALZET mini pump product line, our LACTEL biodegradable polymer product line and certain excipients that are included in REMOXY and other products. Net product revenues were $3.2 million and $2.9 million in the three months ended March 31, 2013 and 2012, respectively. The increase in the three months ended March 31, 2013 was primarily attributable to higher product revenue from our ALZET mini pump product line as a result of higher units sold and price increases for the product line as well as higher product revenue from the sale of certain excipients included in REMOXY to Pfizer, partially offset by lower revenue from our LACTEL polymer product line as a result of fewer units sold in the three months ended March 31, 2013 compared to the corresponding period in 2012.

***Cost of product revenues.*** Cost of product revenues was $1.7 million and $1.5 million for the three months ended March 31, 2013 and 2012. The increase in the cost of product revenue in the three months ended March 31, 2013 compared to the corresponding period in 2012 was primarily the result of and higher scrap expense associated with our LACTEL product line and higher cost of goods sold related to the sale of certain excipients to Pfizer, partially offset by lower cost of goods sold from our ALZET product line

20

Table of Contents

arising from lower manufacturing costs for products sold in the first quarter of 2013. Cost of product revenue and gross profit margin will fluctuate from period to period depending upon the product mix in a particular period and unit volumes sold. Stock-based compensation expense recognized related to cost of product revenues was $49,000 and $64,000 for the three months ended March 31, 2013 and 2012, respectively.

As of March 31, 2013 and 2012, we had 23 manufacturing employees. We expect the number of employees involved in manufacturing will remain comparable in the near future.

***Research and development***. Research and development expenses are primarily comprised of salaries, benefits, stock-based compensation and other compensation cost associated with research and development personnel, overhead and facility costs, preclinical and non-clinical development costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. Research and development expenses were $4.8 million and $5.6 million for the three months ended March 31, 2013 and 2012, respectively. The decrease in the three months ended March 31, 2013 was primarily attributable to lower development costs associated with Relday, REMOXY, TRANSDUR-Sufentanil, ELADUR, ORADUR-ADHD, partially offset by higher development costs associated with POSIDUR, depot injectable programs and other research programs compared to the corresponding period in 2012 as more fully discussed below. Stock-based compensation expense recognized related to research and development personnel was $570,000 and $698,000 for the three months ended March 31, 2013 and 2012, respectively.

Research and development expenses associated with our major development programs approximate the following (in thousands):

| | Three months ended March 31, | |
|---|---|---|
| | **2013** | **2012** |
| POSIDUR (1) | $ 2,747 | $ 2,349 |
| Depot Injectable Programs | 981 | 713 |
| Relday (1) | 174 | 1,009 |
| REMOXY and other ORADUR-based opioid products licensed to Pain Therapeutics (1) | 54 | 587 |
| TRANSDUR-Sufentanil | 34 | 71 |
| ORADUR-ADHD | 26 | 211 |
| ELADUR (1) | 5 | 32 |
| Others | 768 | 662 |
| Total research and development expenses | $ 4,789 | $ 5,634 |

(1) See Note 2 Strategic Agreements in the condensed financial statements for more details about our agreements with Hospira, Nycomed, Pfizer, Pain Therapeutics and Zogenix.

*POSIDUR*

Our research and development expenses for POSIDUR increased to $2.7 million in the three months ended March 31, 2013 from $2.3 million in the corresponding period in 2012 primarily due to higher expenses related to preparation of the POSIDUR NDA in the first quarter of 2013 compared with the corresponding period in 2012.

*Depot Injectable programs*

Our research and development expenses for depot injectable programs increased to $981,000 in the three months ended March 31, 2013 from $713,000 in the corresponding period in 2012, primarily due to higher external costs and employee-related costs for these programs.

*Relday*

Our research and development expenses for Relday decreased to $174,000 in three months ended March 31, 2013 from $1.0 million in the corresponding period in 2012 primarily due to lower employee-related cost as well as lower costs related to formulation development and non-clinical studies associated with Relday.

*REMOXY and other select ORADUR-based opioid products*

Our research and development expenses for REMOXY and other opioids partnered with Pain Therapeutics decreased to $54,000 in the three months ended March 31, 2013 from $587,000 in the corresponding period in 2012. The decrease in the three months ended March 31, 2013 was primarily due to lower employee-related cost as well as lower external costs related to REMOXY.

Table of Contents

*TRANSDUR-Sufentanil*

Our research and development expenses for TRANSDUR-Sufentanil decreased to $34,000 in the three months ended March 31, 2013 from $71,000 in the corresponding period in 2012, primarily due to decreased external costs and employee-related costs for this drug candidate.

*ORADUR-ADHD*

Our research and development expenses for ORADUR-ADHD decreased to $26,000 in the three months ended March 31, 2013 from $211,000 in the corresponding period in 2012, primarily due to lower employee-related costs for this drug candidate.

*ELADUR*

Our research and development expenses for ELADUR decreased to $5,000 in the three months ended March 31, 2013 from $32,000 in the corresponding period in 2012, primarily due to lower employee-related costs related to this product candidate.

*Other DURECT research programs*

Our research and development expenses for all other programs increased to $768,000 in the three months ended March 31, 2013 from $662,000 in the corresponding period in 2012, primarily due to higher employee-related costs for these research programs.

As of March 31, 2013, we had 55 research and development employees compared with 56 as of March 31, 2012. We expect research and development expenses to decrease modestly in the near future.

We cannot reasonably estimate the timing and costs of our research and development programs due to the risks and uncertainties associated with developing pharmaceuticals, as outlined in the Risk Factors section of this report. The duration of development of our research and development programs may span as many as ten years or more, and estimation of completion dates or costs to complete would be highly speculative and subjective due to the numerous risks and uncertainties associated with developing pharmaceutical products, including significant and changing government regulation, the uncertainties of future preclinical and clinical study results, the uncertainties with our collaborators commitment and progress to the programs and the uncertainties associated with process development and manufacturing as well as sales and marketing. In addition, with respect to our development programs subject to third-party collaborations, the timing and expenditures to complete the programs are subject to the control of our collaborators. Therefore, we cannot reasonably estimate the timing and estimated costs of the efforts necessary to complete the research and development programs. For additional information regarding these risks and uncertainties, see Risk Factors below.

***Selling, general and administrative.*** Selling, general and administrative expenses are primarily comprised of salaries, benefits, stock-based compensation and other compensation cost associated with finance, legal, business development, sales and marketing and other administrative personnel, overhead and facility costs, and other general and administrative costs. Selling, general and administrative expenses were $2.9 million for the three months ended March 31, 2013, compared to $3.3 million for the corresponding period in 2012. The decrease in selling, general and administrative expenses was primarily due to lower employee-related costs as well as lower patent-related expenses incurred in the three months ended March 31, 2013. Stock-based compensation expense recognized related to selling, general and administrative personnel was $326,000 and $414,000 for the three months ended March 31, 2013 and 2012, respectively.

As of March 31, 2013 and 2012, we had 26 selling, general and administrative personnel. We expect selling, general and administrative expenses to remain comparable in the near future.

***Other income (expense).*** Interest and other income was $14,000 for the three months ended March 31, 2013, compared to $21,000 for the corresponding period in 2012. The decrease in interest income was primarily the result of lower average cash and investment balances during the three months ended March 31, 2013 compared to the corresponding period in 2012.

Interest expense was $2,000 for both three months periods ended March 31, 2013 and 2012.

***Liquidity and Capital Resources***

We had cash, cash equivalents and investments totaling $25.5 million at March 31, 2013 compared to $28.9 million at December 31, 2012. These balances include $300,000 and $400,000 of interest-bearing marketable securities classified as restricted investments on our balance sheets as of March 31, 2013 and December 31, 2012, respectively. The decrease in cash, cash equivalents and investments during the three

months ended March 31, 2013 was primarily the result of ongoing operating expenses, partially offset by payments received from customers.

We used $3.4 million of cash in operating activities for the three months ended March 31, 2013 compared to $4.4 million for the corresponding period in 2012. The cash used for operations was primarily to fund operations as well as our working capital

Table of Contents

requirements. Our cash used in operating activities differs from our net income (loss) primarily due to the timing and recognition of up-front payments under collaborative agreements. Upfront payments received upon execution of collaborative agreements are recorded as deferred revenue and generally recognized on a straight-line basis over the period of our continuing involvement with the third-party collaborator pursuant to the applicable agreement. The net income of $30.8 million for the three months ended March 31, 2012 was largely a result of the accelerated recognition of $35.4 million in deferred revenue associated with upfront fees previously received from terminated collaboration agreements; such revenue is non-recurring and has no cash flow impact on the Company. The decrease in cash used for operations was also attributable to the increases in accounts receivable and prepaid expenses and other assets, partially offset by the decreases in accounts payable, accrued liabilities and deferred revenue for the three months ended March 31, 2013 compared to the corresponding period in 2012.

We received $432,000 of cash from investing activities for the three months ended March 31, 2013 compared to $3.1 million of cash received for the corresponding period in 2012. The decrease in cash received from investing activities was primarily due to a decrease in net proceeds from maturities of available-for-sale securities for the three months ended March 31, 2013 compared to the corresponding period in 2012. We anticipate incurring capital expenditures of approximately $100,000 over the next 12 months to purchase research and development and other capital equipment. The amount and timing of these capital expenditures will depend on, among other things, the timing of clinical trials for our products and our collaborative research and development activities.

There were no net cash flows from financing activities for the three months ended March 31, 2013 compared to $2,000 of cash used for the corresponding period in 2012. The decrease in cash used in financing activities was primarily a result of slightly higher proceeds received from exercises of stock options in the three months ended March 31, 2013 compared to the corresponding period in 2012.

We anticipate that cash used in operating and investing activities will increase modestly in the near future as more of our research and development is for internal programs with expenses not reimbursed by a collaborator, pending our efforts to sign new collaborators or experience an increase in research and development activities under existing collaborations.

During the three months ended March 31, 2013, we believe there have been no significant changes in our commercial commitments and contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

We believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations, existing debt and contractual commitments, and planned capital expenditures through at least the next 12 months. We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. Additionally, we do not expect to generate meaningful revenues from our pharmaceutical product candidates currently under development for at least the next twelve months, if at all. Depending on whether we enter into additional collaborative agreements in the near term, we may be required to raise additional capital through a variety of sources, including:

- the public equity markets;
- private equity financings;
- collaborative arrangements; and/or
- public or private debt.

There can be no assurance that we will enter into additional collaborative agreements in the near term or additional capital will be available on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain of our products, technologies or potential markets, either of which could have a material adverse effect on our business, financial condition and results of operations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to our existing stockholders.

Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. We select investments that maximize interest income to the extent possible given these two constraints. We satisfy liquidity requirements by investing excess cash in

securities with different maturities to match projected cash needs and limit concentration of credit risk by diversifying our investments among a variety of high credit-quality issuers.

***Off-Balance Sheet Arrangements***

We have not utilized off-balance sheet arrangements to fund our operations or otherwise manage our financial position.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

During the three months ended March 31, 2013, we believe there have been no significant changes in market risks as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

Table of Contents

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures*: The Company s principal executive and financial officers reviewed and evaluated the Company s disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 10-Q. Based on that evaluation, the Company s principal executive and financial officers concluded that the Company s disclosure controls and procedures are effective at ensuring that information required to be disclosed by the Company in reports that the Company files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to management, including the Company s principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

*Changes in Internal Control Over Financial Reporting*: There were no significant changes in the Company s internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) during the Company s most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

Table of Contents

## PART II OTHER INFORMATION

### Item 1. Legal Proceedings

We are not a party to any material legal proceedings.

### Item 1A. Risk Factors

In addition to the other information in this Form 10-Q, a number of factors may affect our business and prospects. These factors include but are not limited to the following, which you should consider carefully in evaluating our business and prospects. Changes to our risk factors contained below relate primarily to updates in the development of our product candidates, financial condition and intellectual property position.

**Risks Related To Our Business**

*Development of our pharmaceutical product candidates is not complete, and we cannot be certain that our product candidates will be able to be commercialized*

To be profitable, we or our third-party collaborators must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our pharmaceutical product candidates under development. For each product candidate that we or our third-party collaborators intend to commercialize, we must successfully meet a number of critical developmental milestones for each disease or medical condition targeted, including:

- selecting and developing a drug delivery platform technology to deliver the proper dose of drug over the desired period of time;
- determining the appropriate drug dosage for use in the pharmaceutical product candidate;
- developing drug compound formulations that will be tolerated, safe and effective and that will be compatible with the system;
- demonstrating the drug formulation will be stable for commercially reasonable time periods;
- demonstrating through clinical trials that the drug and system combination is safe and effective in patients for the intended indication; and
- completing the manufacturing development and scale-up to permit manufacture of the pharmaceutical product candidate in commercial quantities and at acceptable prices.

The time frame necessary to achieve these developmental milestones for any individual product is long and uncertain, and we may not successfully complete these milestones for any of our products in development. We have not yet completed development of POSIDUR, TRANSDUR-Sufentanil, ELADUR, Relday, REMOXY and our other ORADUR-based drug candidates, and we have limited experience in developing such products. We may not be able to finalize the design or formulation of any of these product candidates. In addition, we may select components, solvents, excipients or other ingredients to include in our product candidates that have not been previously approved for use in pharmaceutical products, which may require us or our collaborators to perform additional studies and may delay clinical testing and regulatory approval of our product candidates. Even after we complete the design of a product candidate, the product candidate must still complete required clinical trials and additional safety testing in animals before approval for commercialization. We are continuing testing and development of our product candidates and may explore possible design or formulation changes to address issues of safety, manufacturing efficiency and performance. We or our collaborators may not be able to complete development of any product candidates that will be safe and

effective and that will have a commercially reasonable treatment and storage period. If we or our third-party collaborators are unable to complete development of POSIDUR, TRANSDUR-Sufentanil, ELADUR, Relday, REMOXY and our ORADUR-based drug candidates, or other product candidates, we will not be able to earn revenue from them, which would materially harm our business.

*We or our third-party collaborators must show the safety and efficacy of our drug candidates in animal studies and human clinical trials to the satisfaction of regulatory authorities before they can be sold; failure to obtain approvals for REMOXY, POSIDUR or our other product candidates would significantly harm our business, prospects and financial condition*

Before we or our third-party collaborators can obtain government approval to sell any of our pharmaceutical product candidates, we or they, as applicable, must demonstrate through laboratory performance studies and safety testing, nonclinical (animal) studies and clinical (human) trials that each system is safe and effective for human use for each targeted indication. The clinical development status of our most advanced publicly announced development programs is as follows:

REMOXY In December 2010, King (now Pfizer) resubmitted the NDA in response to a Complete Response Letter received in December 2008 by Pain Therapeutics. On June 23, 2011, a Complete Response Letter from the FDA was received by Pfizer on the resubmission to the NDA for REMOXY. The issues raised in the Complete Response Letter relate primarily to manufacturing. Pfizer has efforts underway to resolve these issues. On April 30, 2013, Pfizer stated that it had a

Table of Contents

productive meeting regarding REMOXY with the FDA in late March and had received guidance that is helping to inform the next steps in addressing the issues raised by the FDA in the Complete Response Letter. Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the FDA s Complete Response Letter and they may never be resolved. Further, there can be no assurance that Pfizer will not decide at some point to discontinue development of REMOXY.

POSIDUR A total of 15 clinical trials in subjects undergoing various surgical procedures have been conducted with POSIDUR. In all, 1,060 subjects have been studied in the POSIDUR Phase 2 and 3 clinical development program, of which 668 have been treated with POSIDUR, 268 with SABER-Placebo (SABER vehicle without drug), and 124 with bupivacaine HCl solution. In July 2012, we completed pre-NDA communications with the FDA regarding POSIDUR. Through this process, we have received guidance and thoughtful comments from the FDA covering various chemistry, manufacturing, non-clinical, clinical pharmacology, clinical, statistical and product labeling topics based on our pre-NDA meeting questions. In April 2013, we submitted a new drug application as a 505(b)(2) application, which relies in part on the FDA s findings of safety and effectiveness of a reference drug. We expect that the FDA will notify us whether our NDA submission has been accepted for filing in June 2013. If accepted for filing, the FDA would be expected to assign a Prescription Drug User Fee Act (PDUFA) target date (the date the FDA expects to complete its review of the POSIDUR NDA) in the first quarter of 2014. There can be no assurance that such an NDA submission will be accepted for review by the FDA or that marketing approval will occur by the FDA or other regulatory agencies. The FDA may require additional clinical trials or additional data before accepting the NDA or granting marketing approval.

TRANSDUR-Sufentanil Patch In February 2009, an end-of-Phase II meeting with the FDA was conducted for this program outlining a potential regulatory pathway for the Phase III program and NDA submission. In 2011, we had discussions with the FDA and regulatory agencies in several major European countries to better understand development requirements for U.S. and European countries. We are in discussions with potential partners regarding licensing development and commercialization rights to this program to which we hold worldwide rights. There can be no assurance that our planned development program for TRANSDUR-Sufentanil will generate data and information that will be deemed sufficient for marketing approval by the FDA or other regulatory agencies or that we will be able to find a collaborator with respect to the development and commercialization of this drug candidate.

ELADUR A Phase IIa clinical trial in post-herpetic neuralgia (PHN or post-shingles pain) was completed and positive efficacy trends were reported in the fourth quarter of 2007. King, which assumed worldwide development and commercialization rights for ELADUR through its acquisition of Alpharma, conducted a Phase II clinical trial to evaluate ELADUR for the treatment of chronic low back pain and reported in April 2011 that the primary efficacy endpoint for the trial was not met. In February 2012, Pfizer, which assumed worldwide development and commercialization rights to ELADUR through its acquisition of King, notified us that they were returning their worldwide development and commercialization rights to ELADUR. We are in discussions with potential partners regarding licensing development and commercialization rights to this program to which we hold worldwide rights. There can be no assurance that our planned development program for ELADUR will generate data and information that will be deemed sufficient for marketing approval by the FDA or other regulatory agencies or that we will be able to find a collaborator with respect to the development and commercialization of this drug candidate.

ORADUR-based opioids Phase I clinical trials have been conducted for two of these ORADUR-based products (hydrocodone and hydromorphone), and an IND has been accepted by the FDA for the third ORADUR-based opioid (oxymorphone). There can be no assurance that we or our collaborators will be able to successfully develop ORADUR-based formulations of hydrocodone, hydromorphone or oxymorphone to obtain marketing approval by the FDA or other regulatory agencies.

ORADUR-ADHD Since 2010, we and Orient Pharma have conducted several Phase I studies to evaluate multiple formulations of ORADUR-ADHD. Based on information from these trials, we are continuing to evaluate the lead formulations and are planning next steps in the ORADUR-ADHD program. There can be no assurance that we will be able to successfully develop ORADUR-ADHD to obtain marketing approval by the FDA or other regulatory agencies.

Relday In January 2013, Zogenix announced positive single-dose pharmacokinetic (PK) results from the Phase 1 clinical trial of Relday. Per Zogenix, based on the favorable safety and PK profile demonstrated with the 25 mg and 50 mg once-monthly doses

tested in the Phase 1 trial, Zogenix extended the study to include a 100 mg dose of the same formulation. In May 2013, Zogenix announced positive results with the 100 mg arm, demonstrating dose proportionality across the full dose range that would be anticipated to be used in clinical practice. Zogenix also stated that it has initiated efforts to secure a development and commercialization partner for Relday. There can be no assurance that Zogenix will succeed in securing a development and commercialization partner for Relday or if and when further development of this drug candidate will occur.

We are currently in the clinical, preclinical or research stages with respect to all our other product candidates under development. We plan to continue extensive and costly tests, clinical trials and safety studies in animals to assess the safety and effectiveness of our product candidates. These studies include laboratory performance studies and safety testing, clinical trials and

Table of Contents

animal toxicological studies necessary to support regulatory approval of development products in the United States and other countries of the world. These studies are costly, complex and last for long durations, and may not yield data supportive of the safety or efficacy of our drug candidates or required for regulatory approval.

*Early clinical trial results may not predict the results of later trials, and our clinical trials or those of our collaborators for POSIDUR or REMOXY may not satisfy regulatory agencies*

While some clinical trials of our product candidates have shown indications of safety and efficacy of our product candidates, there can be no assurance that these results will be confirmed in subsequent clinical trials or provide a sufficient basis for regulatory approval. In addition, side effects observed in clinical trials, or other side effects that appear in later clinical trials, may adversely affect our or our collaborators ability to obtain regulatory approval or market our product candidates. For example, in the Phase IIb hysterectomy trial and the BESST Phase III abdominal surgery trial of POSIDUR, transient local hematoma-like discolorations were observed near the surgical site. Side effects such as these, toxicity or other safety issues associated with the use of our drug candidates could require us to perform additional studies or halt development of our drug candidates. We or our collaborators may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of our pharmaceutical product candidates which we have not planned or anticipated. For example, the FDA s Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. There can be no assurance that Pfizer will resolve these issues to the satisfaction of the FDA in a timely manner or ever, which could harm our business, prospects and financial condition. We may also be required to conduct additional clinical trials of POSIDUR, which would be expensive and could delay product approval, harming our business, prospects and financial condition.