DURECT CORP
Form 10-Q
May 03, 2013
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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.

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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.

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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.

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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.

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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).

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	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.

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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.

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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.

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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.

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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.

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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%		

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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.

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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.

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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

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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).

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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.

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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.

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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

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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

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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.

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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

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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.

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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.

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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

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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

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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.

Pfizer is developing products that may compete with REMOXY, and so may decide to discontinue its development

We rely on Pfizer and its subsidiaries to devote time and resources to the development, manufacturing and commercialization of REMOXY. Pfizer and its subsidiaries and affiliates may commercialize, develop or acquire drugs or drug candidates that may compete directly or compete for resources with REMOXY. For instance, Pfizer is developing ALO-02 (an extended release abuse resistant formulation of oxycodone that would compete with REMOXY) and owns Embeda® (an extended-release oral formulation of morphine sulfate), and Avinza® (a once-daily morphine treatment for moderate to severe pain). There can be no assurance that these other drugs or drug candidates in the Pfizer corporate family will not become competitive with REMOXY. If time and resources devoted are limited or there is a failure to fund the continued development of REMOXY, or there is otherwise a failure to perform as we expect, we may not achieve clinical and regulatory milestones and regulatory submissions and related product introductions may be delayed or prevented, and revenues that we would receive from these activities will be less than expected.

Regulatory approval of our product candidates is subject to delay, which could harm our business

Although we have submitted an NDA for POSIDUR, the FDA may not accept any such application in a timely manner or may deny the application entirely. The preclinical and clinical data in such application are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The failure to adequately demonstrate the safety and effectiveness of a pharmaceutical product candidate under development to the satisfaction of FDA and other regulatory agencies could delay or prevent regulatory clearance of the potential product candidate, resulting in delays to the commercialization of our product candidate, and could materially harm our business. Clinical trials may not demonstrate the sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our product candidates, and thus our product candidates may not be approved for marketing. During the review process, the FDA may also request more information regarding the chemistry, manufacturing or controls related to our product candidates, as they have in their complete response letter for REMOXY, and answering such questions could require significant additional work and expense, and take a significant amount of time, resulting in a material delay of approval or the failure to obtain approval.

Regulatory action or failure to obtain product approvals could delay or limit development and commercialization of our product candidates and result in failure to achieve anticipated revenues

The manufacture and marketing of our pharmaceutical product candidates and our research and development activities are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. We or our third-party collaborators must obtain clearance or approval from applicable regulatory authorities before we or they, as applicable, can perform clinical trials, market or sell our products in development in the United States or abroad. Clinical trials, manufacturing and marketing of products are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. In particular, recent recalls of and reported adverse side effects of marketed drugs have made regulatory agencies, including the FDA, increasingly focus on the safety of drug products. Regulatory agencies are requiring more extensive and ever increasing showings of safety at every stage of drug development and commercialization from initial clinical trials to regulatory approval and beyond. These rigorous and evolving standards may delay and increase the expenses of our development efforts. The FDA or other foreign regulatory agency may, at any time, halt our and our collaborators

development and commercialization activities due to safety concerns, in which case our business will be harmed. In addition, the FDA or other foreign regulatory agency may refuse or delay approval of our or our collaborators drug candidates for failure to collect sufficient clinical or animal safety data, and require us or our collaborators to conduct additional clinical or animal safety studies which may cause lengthy delays and increased costs to our programs.

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The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. These laws and regulations are complex and subject to change. Furthermore, these laws and regulations may be subject to varying interpretations, and we may not be able to predict how an applicable regulatory body or agency may choose to interpret or apply any law or regulation to our pharmaceutical product candidates. As a result, clinical trials and regulatory approval can take a number of years to accomplish and require the expenditure of substantial resources. We or our third-party collaborators, as applicable, may encounter delays or rejections based upon administrative action or interpretations of current rules and regulations. We or our third-party collaborators, as applicable, may not be able to timely reach agreement with the FDA on our clinical trials or on the required clinical or animal data we or they must collect to continue with our clinical trials or eventually commercialize our product candidates.

We or our third-party collaborators, as applicable, may also encounter delays or rejections based upon additional government regulation from future legislation, administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. We or our third-party collaborators, as applicable, may encounter similar delays in foreign countries. Sales of our pharmaceutical product candidates outside the United States are subject to foreign regulatory standards that vary from country to country.

The time required to obtain approvals from foreign countries may be shorter or longer than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. We or our third-party collaborators, as applicable, may be unable to obtain requisite approvals from the FDA and foreign regulatory authorities, and even if obtained, such approvals may not be on a timely basis, or they may not cover the clinical uses that we specify. If we or our third-party collaborators, as applicable, fail to obtain timely clearance or approval for our development products, we or they will not be able to market and sell our pharmaceutical product candidates, which will limit our ability to generate revenue.

Many of our drug candidates under development, including REMOXY, our other ORADUR-based opioids and TRANSDUR-Sufentanil are subject to mandatory Risk Evaluation and Mitigation Strategy (REMS) programs, which could delay the approval of these drug candidates and increase the cost, burden and liability associated with the commercialization of these drug candidates

On February 6, 2009, the FDA sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drugs continue to outweigh the risks. The affected opioid drugs include brand name and generic products and are formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone.

On April 19, 2011, the Office of National Drug Control Policy (ONDCP) released the Obama Administration s *Epidemic: Responding to America s Prescription Drug Abuse Crisis* a comprehensive action plan to address the national prescription drug abuse epidemic. This plan includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper disposal, and enforcement. In support of the action plan, the FDA announced the elements of a Risk Evaluation and Mitigation Strategy (REMS) that will require all manufacturers of long-acting and extended-release opioids to ensure that training is provided to prescribers of these medications and to develop information that prescribers can use when counseling patients about the risks and benefits of opioid use. The FDA wants drug makers to work together to develop a single system for implementing the REMS strategies.

On July 9, 2012 the FDA approved a REMS for extended-release (ER) and long-acting (LA) opioids. The REMS is part of a federal initiative to address the prescription drug abuse, misuse, and overdose epidemic. The REMS introduces new safety measures designed to reduce risks and improve the safe use of ER/LA opioids, while ensuring access to needed medications for patients in pain. The new ER/LA opioid REMS will affect more than 20 companies that manufacture these opioid analgesics. Under the new REMS, companies will be required to make education programs available to prescribers based on an FDA Blueprint. It is expected that companies will meet this obligation by providing educational grants to continuing education (CE) providers, who will develop and deliver the training. The REMS also will require companies to make available FDA-approved patient education materials on the safe use of these drugs. The companies will be required to perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program.

Many of our drug candidates including REMOXY, our other ORADUR-opioid drug candidates and TRANSDUR-Sufentanil are subject to the REMS requirement. The FDA s REMS requirements have been evolving, and until the contours of required REMS programs are established by the FDA and understood by drug developers and marketers such as ourselves and our collaborators, there may be delays in marketing approvals for these drug candidates. In addition, there may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of drug candidates subject to the REMS requirement, which could negatively impact the commercial benefits to us and our collaborators from the sale of these drug candidates.

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We depend to a large extent on third-party collaborators, and we have limited or no control over the development, sales, distribution and disclosure for our pharmaceutical product candidates which are the subject of third-party collaborative or license agreements

Our performance depends to a large extent on the ability of our third-party collaborators to successfully develop and obtain approvals for our pharmaceutical product candidates. We have entered into agreements with Pain Therapeutics, King (now Pfizer), Orient Pharma, Zogenix and others under which we granted such third parties the right to develop, apply for regulatory approval for, market, promote or distribute REMOXY and other ORADUR-based products, Relday and other product candidates, subject to payments to us in the form of product royalties and other payments. We have limited or no control over the expertise or resources that any collaborator may devote to the development, clinical trial strategy, regulatory approval, marketing or sale of these product candidates, or the timing of their activities. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreement with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Enforcing any of these agreements in the event of a breach by the other party could require the expenditure of significant resources and consume a significant amount of management time and attention. Our collaborators may also conduct their activities in a manner that is different from the manner we would have chosen, had we been developing such product candidates ourselves. Further, our collaborators may elect not to develop or commercialize product candidates arising out of our collaborative arrangements or not devote sufficient resources to the development, clinical trials, regulatory approval, manufacture, marketing or sale of these product candidates. If any of these events occur, we may not recognize revenue from the commercialization of our product candidates based on such collaborations. In addition, these third parties may have similar or competitive products to the ones which are the subject of their collaborations with us, or relationships with our competitors, which may reduce their interest in developing or selling our product candidates. We may not be able to control public disclosures made by some of our third-party collaborators, which could negatively impact our stock price.

Cancellation of our collaboration agreements may impact our near-term revenues and adversely affect potential economic benefits

Our collaboration agreements with third parties typically allow the third party to terminate the agreement by providing notice to us. For example, in January 2012, we were notified that Nycomed was terminating the Development and License Agreement between Nycomed and us relating to the development and commercialization of POSIDUR in Europe and their other licensed territories. In February 2012, we were notified that Pfizer was terminating the worldwide Development and License Agreement between Alpharma (acquired by King which subsequently was acquired by Pfizer) and us relating to the development and commercialization of ELADUR. In March 2012, we were notified that Hospira was terminating the Development and License Agreement between Hospira and us relating to the development and commercialization of POSIDUR in the United States and Canada. Termination of such agreements can lead to a near-term increase in our reported revenues resulting from the immediate recognition of payments that would otherwise have been recognized over time. Termination deprives us of potential future economic benefits under such agreements, and may make it more difficult to enter into agreements with other third parties for use of the assets that were subject to the terminated agreement. Termination of our agreement with Pain Therapeutics or Zogenix could have similar effects.

Our revenues depend on collaboration agreements with other companies. These agreements subject us to obligations which must be fulfilled and also make our revenues dependent on the performance of such third parties. If we are unable to meet our obligations or manage our relationships with our collaborators under these agreements or enter into additional collaboration agreements or if our existing collaborations are terminated, our revenues may decrease. Acquisitions of our collaborators can be disruptive

Our revenues are based to a significant extent on collaborative arrangements with third parties, pursuant to which we receive payments based on our performance of research and development activities set forth in these agreements. We may not be able to fulfill our obligations or attain milestones set forth in any specific agreement, which could cause our revenues to fluctuate or be less than anticipated and may expose us to liability for contractual breach. In addition, these agreements may require us to devote significant time and resources to communicating with and managing our relationships with such collaborators and resolving possible issues of contractual interpretation which may detract from time our management would otherwise devote to managing our operations. Such agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property under collaborations. Such disputes can delay or prevent the development of potential new product candidates, or can lead to lengthy, expensive litigation or arbitration. In general, our collaboration agreements, including our agreements with Pain Therapeutics and King (now Pfizer) with respect to REMOXY and other ORADUR-based products incorporating specified opioids, Orient Pharma with respect to ORADUR-ADHD and Zogenix with respect to Relday, may be terminated by the other party at will or upon specified conditions including, for example, if we fail to satisfy specified performance milestones or if we breach the terms of the agreement. From time to time, our licensees may be the subject of an acquisition by another company. For example, Alpharma was acquired by King in December 2008, in February 2011 King was acquired by Pfizer and, in October 2011 Nycomed was acquired by Takeda. Such transactions can lead to turnover of program staff, a review of development programs and strategies by the acquirer, and other events that can disrupt a program, resulting in program delays or discontinuations.

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If any of our collaborative agreements are terminated or delayed, our anticipated revenues may be reduced or not materialize, and our products in development related to those agreements may not be commercialized.

Our cash flows are likely to differ from our reported revenues

Our revenues will likely differ from our cash flows from revenue-generating activities. 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 period of continuing involvement may also be revised on a prospective basis. For example, in the first quarter of 2012, we revised the period of continuing involvement related to the termination of our collaborations with Nycomed, Hospira, and Pfizer, resulting in the accelerated recognition of approximately $35.4 million in revenue from upfront payments received in earlier periods; this recognition of revenue in the first quarter of 2012 had no impact on cash flow during the period. As of March 31, 2013, we had $1.7 million of deferred revenue, which will be recognized in future periods and may cause our reported revenues to be greater than cash flows from our ongoing revenue-generating activities.

Our revenues also depend on milestone payments based on achievements by our third-party collaborators. Failure of such collaborators to attain such milestones would result in our not receiving additional revenues

In addition to payments based on our performance of research and development activities, our revenues also depend on the attainment of milestones set forth in our collaboration agreements. Such milestones are typically related to development activities or sales accomplishments. While our involvement is necessary to the achievement of development-based milestones, the performance of our third-party collaborators is also required to achieve those milestones. Under our third-party collaborative agreements, our third party collaborators will take the lead in commercialization activities and we are typically not involved in the achievement of sales-based milestones. Therefore, we are even more dependent upon the performance of our third-party collaborators in achieving sales-based milestones. To the extent we and our third-party collaborators do not achieve such development-based milestones or our third-party collaborators do not achieve sales-based milestones, we will not receive the associated revenues, which could harm our financial condition and may cause us to defer or cut-back development activities or forego the exploitation of opportunities in certain geographic territories, any of which could have a material adverse effect on our business.

Our business strategy includes the entry into additional collaborative agreements. We may not be able to enter into additional collaborative agreements or may not be able to negotiate commercially acceptable terms for these agreements

Our current business strategy includes the entry into additional collaborative agreements for the development and commercialization of our pharmaceutical product candidates. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators and require significant time and resources from our officers, business development, legal, and research and development staff. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators, we compete with numerous other third parties with product opportunities as well the collaborators own internal product opportunities. We may not be able to consummate additional collaborative agreements, or we may not be able to negotiate commercially acceptable terms for these agreements. If we do not consummate additional collaborative agreements, we may have to consume money more rapidly on our product development efforts, defer development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business.

We may have difficulty raising needed capital in the future

Our business currently does not generate sufficient revenues to meet our capital requirements and we do not expect that it will do so in the near future. We have expended and will continue to expend substantial funds to complete the research, development and clinical testing of our pharmaceutical product candidates. We will require additional funds for these purposes, to establish additional clinical- and commercial-scale manufacturing arrangements and facilities, and to provide for the marketing and distribution of our product candidates. Additional funds may not be available on acceptable terms, if at all. If adequate funds are unavailable from operations or additional sources of financing, we may have to delay, reduce the scope of or eliminate one or more of our research or development programs which would materially harm our business, financial condition and results of operations.

We believe that our cash, cash equivalents and investments, will be adequate to satisfy our capital needs for at least the next 12 months. However, our actual capital requirements will depend on many factors, including:

- regulatory actions with respect to our product candidates;

continued progress and cost of our research and development programs;

the continuation of our collaborative agreements that provide financial funding for our activities;

success in entering into collaboration agreements and meeting milestones under such agreements;

progress with preclinical studies and clinical trials;

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the time and costs involved in obtaining regulatory clearance;

costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

costs of developing sales, marketing and distribution channels and our ability and that of our collaborators to sell our pharmaceutical product candidates;

costs involved in establishing manufacturing capabilities for clinical and commercial quantities of our product candidates;

competing technological and market developments;

market acceptance of our product candidates;

costs for recruiting and retaining employees and consultants; and

unexpected legal, accounting and other costs and liabilities related to our business.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through equity or debt financings, convertible debt financings, collaborative arrangements with corporate collaborators or other sources, which may be dilutive to existing stockholders and may cause the price of our common stock to decline. In addition, in the event that additional funds are obtained through arrangements with collaborators or other sources, we may have to relinquish rights to some of our technologies or pharmaceutical product candidates that we would otherwise seek to develop or commercialize ourselves. If adequate funds are not available, we may be required to significantly reduce or refocus our product development efforts, resulting in delays in generating future product revenue.

We and our third-party collaborators may not be able to manufacture sufficient quantities of our pharmaceutical product candidates and components to support the clinical and commercial requirements of our collaborators and ourselves at an acceptable cost or in compliance with applicable government regulations, and we have limited manufacturing experience

We or our third-party collaborators to whom we have assigned such responsibility must manufacture our pharmaceutical product candidates and components in clinical and commercial quantities, either directly or through third parties, in compliance with regulatory requirements and at an acceptable cost. The manufacturing processes associated with our product candidates are complex. We and our third-party collaborators, where relevant, have not yet completed development of the manufacturing process for any product candidates or components, including REMOXY and our other ORADUR-based drug candidates, POSIDUR, TRANSDUR-Sufentanil, ELADUR, and Relday. If we and our third-party collaborators, where relevant, fail to timely complete the development of the manufacturing process for our product candidates, we and our third-party collaborators, where relevant, will not be able to timely produce product for clinical trials and commercialization of our product candidates. We have also committed to manufacture and supply product candidates or components under a number of our collaborative agreements with third-party companies. We have limited experience manufacturing pharmaceutical products, and we may not be able to timely accomplish these tasks. If we and our third-party collaborators, where relevant, fail to develop manufacturing processes to permit us to manufacture a product candidate or component at an acceptable cost, then we and our third-party collaborators may not be able to commercialize that product candidate or we may be in breach of our supply obligations to our third-party collaborators.

Our manufacturing facility in Cupertino is a multi-disciplinary site that we have used to manufacture only research and clinical supplies of several of our pharmaceutical product candidates, including POSIDUR, TRANSDUR-Sufentanil, ELADUR, REMOXY and our other ORADUR-based drug candidates, and Relday. We have not manufactured commercial quantities of any of our product candidates. In the future, we intend to develop additional manufacturing capabilities for our product candidates and components to meet our demands and those of our third-party collaborators by contracting with third-party manufacturers and by potentially constructing additional manufacturing space at our facilities in California and Alabama. We have limited experience building and validating manufacturing facilities, and we may not be able to accomplish these tasks in a timely or cost effective manner.

If we and our third-party collaborators, where relevant, are unable to manufacture our pharmaceutical product candidates or components in a timely manner or at an acceptable cost, quality or performance level, and are unable to attain and maintain compliance with applicable regulations, the clinical trials and the commercial sale of our product candidates and those of our third-party collaborators could be delayed. Additionally, we may need to alter our facility design or manufacturing processes, install additional equipment or do additional construction or testing in order to meet regulatory requirements, optimize the production process, increase efficiencies or production capacity or for other reasons, which may result in additional cost to us or delay production of product needed for the clinical trials and commercial launch of our product candidates and those of our third-party collaborators.

We have entered into a supply agreement with Hospira Worldwide, Inc. for clinical and commercial supplies of POSIDUR and a supply agreement with Corium International, Inc. for clinical and commercial supplies of ELADUR. These third parties are currently our sole source for drug product required for development and commercialization of these drug candidates. Furthermore, we and our third-party collaborators, where relevant, may also need or choose to subcontract with additional third-party contractors to perform manufacturing steps of our pharmaceutical product candidates or supply required components for our product candidates. Where third party contractors perform manufacturing services for us, we will be subject to the schedule, expertise and performance of third parties as well as incur significant additional costs. Failure of third parties to perform their obligations could adversely affect our operations, development timeline and financial results.

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If we or our third-party collaborators cannot manufacture our pharmaceutical product candidates or components in time to meet the clinical or commercial requirements of our collaborators or ourselves or at an acceptable cost, our operating results will be harmed.

Failure to comply with ongoing governmental regulations for our pharmaceutical product candidates could materially harm our business in the future

Marketing or promoting a drug is subject to very strict controls. Furthermore, clearance or approval may entail ongoing requirements for post-marketing studies. The manufacture and marketing of drugs are subject to continuing FDA and foreign regulatory review and requirements that we update our regulatory filings. Later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. Any of the following or other similar events, if they were to occur, could delay or preclude us from further developing, marketing or realizing full commercial use of our product candidates, which in turn would materially harm our business, financial condition and results of operations:

- failure to obtain or maintain requisite governmental approvals;
- failure to obtain approvals for clinically intended uses of our pharmaceutical product candidates under development; or
- FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects in our product candidates.

Manufacturers of drugs must comply with the applicable FDA good manufacturing practice regulations, which include production design controls, testing, quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. Compliance with current good manufacturing practices regulations is difficult and costly. Manufacturing facilities are subject to ongoing periodic inspection by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed before they can be used for the commercial manufacture of our development products. We and/or our present or future suppliers and distributors may be unable to comply with the applicable good manufacturing practice regulations and other FDA regulatory requirements. We have not been subject to a good manufacturing regulation inspection by the FDA relating to our product candidates. If we, our third-party collaborators or our respective suppliers do not achieve compliance for our product candidates we or they manufacture, the FDA may refuse or withdraw marketing clearance or require product recall, which may cause interruptions or delays in the manufacture and sale of our product candidates.

We have a history of operating losses, expect to continue to have losses in the future and may never achieve or maintain profitability

We have incurred significant operating losses since our inception in 1998 and, as of March 31, 2013, had an accumulated deficit of approximately $344.5 million. We expect to continue to incur significant operating losses over the next several years as we continue to incur significant costs for research and development, clinical trials, manufacturing, sales, and general and administrative functions. Our ability to achieve profitability depends upon our ability, alone or with others, to successfully complete the development of our proposed product candidates, obtain the required regulatory clearances, and manufacture and market our proposed product candidates. Development of pharmaceutical product candidates is costly and requires significant investment. In addition, we may choose to license from third parties either additional drug delivery platform technology or rights to particular drugs or other appropriate technology for use in our product candidates. The license fees for these technologies or rights would increase the costs of our product candidates.

To date, we have not generated significant revenue from the commercial sale of our pharmaceutical product candidates and do not expect to do so in the near future. Our current revenues are from the sale of the ALZET product line, the sale of LACTEL biodegradable polymers and certain excipient sales, and from payments under collaborative research and development agreements with third parties. In the year ended December 31, 2012, we had a one-time increase in revenues resulting from the recognition of previously deferred revenues associated with upfront payments from terminated agreements. We do not expect this to recur. We do not expect our product revenues to increase significantly in the near future, and we do not expect that collaborative research and development revenues will exceed our actual operating expenses. We do not anticipate meaningful revenues to derive from the commercialization and marketing of our product candidates in development in the near future, and therefore do not expect to generate sufficient revenues to cover expenses or achieve profitability in the near future.

We may develop our own sales force to market future products but we have limited sales experience and may not be able to do so effectively

We may choose to develop our own sales force to market products that we may develop in the future, or to market POSIDUR if we do not enter into an agreement with a third party to commercialize POSIDUR. Developing a sales force will require substantial

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expenditures and the hiring of qualified personnel. We have limited sales and marketing experience, and may not be able to effectively recruit, train or retain sales personnel. If we are not able to put in place an appropriate sales force for POSIDUR before its approval, we may not be able to effectively launch the product. We may not be able to effectively sell our product candidates, if approved, and our failure to do so could limit or materially harm our business.

We and our third-party collaborators may not sell our product candidates effectively

We and our third-party collaborators compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts and those of our third-party collaborations may be unable to compete successfully against these other companies. We and our third-party collaborators, if relevant, may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all. We and our third-party collaborators, if relevant, may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our product candidates;
- cease operations with little or no notice to us;
- offer, design, manufacture or promote competing product lines;
- fail to maintain adequate inventory and thereby restrict use of our product candidates; or
- build up inventory in excess of demand thereby limiting future purchases of our product candidates resulting in significant quarter-to-quarter variability in our sales.

The failure of us or our third-party collaborators to effectively develop, gain regulatory approval for, sell, manufacture and market our product candidates will hurt our business, prospects and financial results.

We rely heavily on third parties to support development, clinical testing and manufacturing of our product candidates

We rely on third-party contract research organizations, service providers and suppliers to provide critical services to support development, clinical testing, and manufacturing of our product candidates. For example, we currently depend on third-party vendors to manage and monitor our clinical trials and to perform critical manufacturing steps for our product candidates. These third parties may not execute their responsibilities and tasks competently in compliance with applicable laws and regulations or in a timely fashion. We rely on third-parties to manufacture or perform manufacturing steps relating to our product candidates or components. We anticipate that we will continue to rely on these and other third-party contractors to support development, clinical testing, and manufacturing of our product candidates. Failure of these contractors to provide the required services in a competent or timely manner or on reasonable commercial terms could materially delay the development and approval of our development products, increase our expenses and materially harm our business, financial condition and results of operations.

Key components of our product candidates are provided by limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs

Certain components and drug substances used in our product candidates (including POSIDUR, TRANSDUR-Sufentanil, ELADUR, REMOXY, our other ORADUR-based drug candidates, and Relday) are currently purchased from a single or a limited number of outside sources. In particular, Eastman Chemical is the sole supplier, pursuant to a supply agreement entered into in December 2005, of our requirements of sucrose acetate isobutyrate, a necessary component of POSIDUR, REMOXY, our other ORADUR-based drug candidates, Relday and certain other

pharmaceuticals systems we have under development. The reliance on a sole or limited number of suppliers could result in:

- delays associated with redesigning a pharmaceutical product candidate due to a failure to obtain a single source component;
- an inability to obtain an adequate supply of required components; and
- reduced control over pricing, quality and delivery time.

We have supply agreements in place for certain components of our pharmaceutical product candidates, but do not have in place long term supply agreements with respect to all of the components of any of our product candidates. Therefore the supply of a particular component could be terminated at any time without penalty to the supplier. In addition, we may not be able to procure required components or drugs from third-party suppliers at a quantity, quality and cost acceptable to us. Any interruption in the supply of single source components could cause us to seek alternative sources of supply or manufacture these components internally. Furthermore, in some cases, we are relying on our third-party collaborators to procure supply of necessary components. If the supply of any components for our product candidates is interrupted, components from alternative suppliers may not be available in sufficient volumes or at acceptable quality levels within required timeframes, if at all, to meet our needs or those of our third-party collaborators. This could delay our ability to complete clinical trials and obtain approval for commercialization and marketing of our product candidates, causing us to lose sales, incur additional costs, delay new product introductions and could harm our reputation.

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If we are unable to adequately protect, maintain or enforce our intellectual property rights or secure rights to third-party patents, we may lose valuable assets, experience reduced market share or incur costly litigation to protect our rights or our third-party collaborators may choose to terminate their agreements with us

Our ability to commercially exploit our products will depend significantly on our ability to obtain and maintain patents, maintain trade secret protection and operate without infringing the proprietary rights of others.

The patent status of our lead drug candidates, REMOXY and POSIDUR, are as follows:

In the U.S., REMOXY is covered by six patent families. Three patent families include granted patents expiring in at least 2015, 2025, and 2031, respectively. The patent family providing protection until at least 2025 includes six granted patents. The other three patent families include pending patent applications, which if granted, could result in patents expiring in 2028, 2034, and 2034, respectively, plus any eligible patent term adjustments and extensions. We currently have pending U.S. applications for these six patent families. There can be no assurance that the pending patent applications will be granted. In Europe, REMOXY is covered by two granted patents expiring in 2016 and 2023, respectively, plus any eligible patent term extensions.

In the U.S., POSIDUR is covered by two patent families, which include granted patents expiring in at least 2015 and 2025, respectively. In Europe, POSIDUR is covered by two granted patents expiring in 2016 and 2025, respectively, plus any eligible patent term extensions.

As of April 19, 2013, we held 54 issued U.S. patents and 350 issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have 63 pending U.S. patent applications and have filed 109 patent applications under the Patent Cooperation Treaty, from which 139 national phase applications are currently pending in Europe, Australia, Japan, Canada and other countries.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patent applications or those that are licensed to us may not issue into patents, and any issued patents may not provide protection against competitive technologies or may be held invalid if challenged. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to us or licensed by us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

The patent laws of the U.S. have recently undergone changes through court decisions which may have significant impact on us and our industry. Decisions of the U.S. Supreme Court (e.g., *KSR v. Teleflex, eBay v. MercExchange*) and other courts with respect to the standards of patentability, enforceability, availability of injunctive relief and damages may make it more difficult for us to procure, maintain and enforce patents. In addition, the America Invents Act was signed into law in September 2011, which among other changes to the U.S. patent laws, changes patent priority from first to invent to first to file, implements a post-grant opposition system for patents and provides for a prior user defense to infringement. These judicial and legislative changes have introduced significant uncertainty in the patent law landscape and may potentially negatively impact our ability to procure, maintain and enforce patents to provide exclusivity for our products.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances, and that all inventions arising out of the individual s relationship with us will be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology.

We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology. We may have to resort to litigation to protect our intellectual property rights, or to determine their scope, validity or enforceability. In addition, interference, derivation, post-grant oppositions, and similar proceedings may be necessary to determine rights to inventions in our patents and patent applications. Enforcing or defending our proprietary rights is expensive, could cause diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

Our collaboration agreements may depend on our intellectual property

We are party to collaborative agreements with Pain Therapeutics, King (now Pfizer) and Zogenix among others. Our third-party collaborators have entered into these agreements based on the exclusivity that our intellectual property rights confer on the products being developed. The loss or diminution of our intellectual property rights could result in a decision by our third-party collaborators to

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terminate their agreements with us. In addition, these agreements are generally complex and contain provisions that could give rise to legal disputes, including potential disputes concerning ownership of intellectual property and data under collaborations. Such disputes can lead to lengthy, expensive litigation or arbitration requiring us to devote management time and resources to such dispute which we would otherwise spend on our business. To the extent that our agreements call for future royalties to be paid conditional on our having patents covering the royalty-bearing subject matter, the decision by the Supreme Court in the case of *MedImmune v. Genentech* could encourage our licensees to challenge the validity of our patents and thereby seek to avoid future royalty obligations without losing the benefit of their license. Should they be successful in such a challenge, our ability to collect future royalties could be substantially diminished.

We may be sued by third parties which claim that our product candidates infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical patents

We or our collaborators may be exposed to future litigation by third parties based on claims that our product candidates or activities infringe the intellectual property rights of others or that we or our collaborators have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents and the breadth and scope of trade secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us or our collaborators, whether or not valid, could result in substantial costs, could place a significant strain on our financial resources and could harm our reputation. We also may not have sufficient funds to litigate against parties with substantially greater resources. In addition, pursuant to our collaborative agreements, we have provided our collaborators with the right, under specified circumstances, to defend against any claims of infringement of the third party intellectual property rights, and such collaborators may not defend against such claims adequately or in the manner that we would do ourselves. Intellectual property litigation or claims could force us or our collaborators to do one or more of the following, any of which could harm our business or financial results:

- cease selling, incorporating or using any of our pharmaceutical product candidates that incorporate the challenged intellectual property, which would adversely affect our revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our product candidates, which would be costly and time-consuming.

Technologies and businesses which we acquire or license may be difficult to integrate, disrupt our business, dilute stockholder value or divert management attention.

We may acquire technologies, products or businesses to broaden the scope of our existing and planned product lines and technologies. Future acquisitions expose us to:

- increased costs associated with the acquisition and operation of the new businesses or technologies and the management of geographically dispersed operations;
- the risks associated with the assimilation of new technologies, operations, sites and personnel;
- the diversion of resources from our existing business and technologies;
- the inability to generate revenues to offset associated acquisition costs;

the requirement to maintain uniform standards, controls, and procedures; and

the impairment of relationships with employees and customers or third party collaborators as a result of any integration of new management personnel.

Acquisitions may also result in the issuance of dilutive equity securities, the incurrence or assumption of debt or additional expenses associated with the amortization of acquired intangible assets or potential businesses. Past acquisitions, such as our acquisitions of IntraEAR, ALZET, SBS and APT, as well as future acquisitions, may not generate any additional revenue or provide any benefit to our business.

Some of our pharmaceutical product candidates contain controlled substances, the making, use, sale, importation and distribution of which are subject to regulation by state, federal and foreign law enforcement and other regulatory agencies

Some of our product candidates currently under development contain, and our products in the future may contain, controlled substances which are subject to state, federal and foreign laws and regulations regarding their manufacture, use, sale, importation and distribution. The TRANSDUR-Sufentanil patch, REMOXY and our other ORADUR-based drug candidates, and other product candidates we have under development contain active ingredients which are classified as controlled substances under the regulations of the U.S. Drug Enforcement Agency. For our product candidates containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal

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and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation and distribution of controlled substances. These regulations are extensive and include regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, record keeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of drug candidates including controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of our product candidates containing controlled substances. In particular, among other things, there is a risk that these regulations may interfere with the supply of the drugs used in our clinical trials, and in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand.

Write-offs related to the impairment of long-lived assets, inventories and other non-cash charges, as well as stock-based compensation expenses may adversely impact or delay our profitability

We may incur significant non-cash charges related to impairment write-downs of our long-lived assets, including goodwill and other intangible assets. We will continue to incur non-cash charges related to amortization of other intangible assets. For example, we had a $13.5 million non-cash write-down of deferred royalties and commercial rights related to CHRONOGESIC in the fourth quarter of 2008. We are required to perform periodic impairment reviews of our goodwill at least annually. The carrying value of goodwill on our balance sheet was $6.4 million at March 31, 2013. To the extent these reviews conclude that the expected future cash flows generated from our business activities are not sufficient to recover the cost of our long-lived assets, we will be required to measure and record an impairment charge to write-down these assets to their realizable values. We completed our last review during the fourth quarter of 2012 and determined that goodwill was not impaired as of December 31, 2012. However, there can be no assurance that upon completion of subsequent reviews a material impairment charge will not be recorded. If future periodic reviews determine that our assets are impaired and a write-down is required, it will adversely impact or delay our profitability.

Inventories include certain excipients that are sold to a customer and included in products awaiting regulatory approval. These inventories are capitalized based on management s judgment of probable sale prior to their expiration date which in turn is based on non-binding forecasts from our customer. The valuation of inventory requires us to estimate the value of inventory that may become expired prior to use. We may be required to expense previously capitalized inventory costs upon a change in our judgment, due to, among other potential factors, a denial or delay of approval of our customer s product by the necessary regulatory bodies, or new information that suggests that the inventory will not be saleable. In addition, these circumstances may cause us to record a liability related to minimum purchase agreements that we have in place for raw materials.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents, short-term investments or long-term investments and our ability to meet our financing objectives

Our cash and cash equivalents are maintained in highly liquid investments with remaining maturities of 90 days or less at the time of purchase. Our short-term investments consist primarily of readily marketable debt securities with original maturities of greater than 90 days from the date of purchase but remaining maturities of less than one year from the balance sheet date. Our long-term investments consist primarily of readily marketable debt securities with maturities in one year or beyond from the balance sheet date. While, as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents, short-term investments or long-term investments since March 31, 2013, no assurance can be given that deterioration in conditions of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents, short-term investments or long-term investments or our ability to meet our financing objectives.

We depend upon key personnel who may terminate their employment with us at any time, and we may need to hire additional qualified personnel

Our success will depend to a significant degree upon the continued services of key management, technical and scientific personnel, including Felix Theeuwes, our Chairman and Chief Scientific Officer, and James E. Brown, our President and Chief Executive Officer. In addition, our success will depend on our ability to attract and retain other highly skilled personnel. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to product development or approval, loss of sales and diversion of management resources.

We may not successfully manage our company through varying business cycles

Our success will depend on properly sizing our company through growth and contraction cycles caused in part by changing business conditions, which places a significant strain on our management and on our administrative, operational and financial resources. To manage through such cycles, we must expand or contract our facilities, our operational, financial and management systems and our personnel. If we were unable to manage growth and contractions effectively our business would be harmed.

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Our business involves environmental risks and risks related to handling regulated substances

In connection with our research and development activities and our manufacture of materials and pharmaceutical product candidates, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the use, generation and disposal of hazardous materials, including but not limited to certain hazardous chemicals, solvents, agents and biohazardous materials. The extent of our use, generation and disposal of such substances has increased substantially since we started manufacturing and selling biodegradable polymers. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances generated by us, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Our corporate headquarters, manufacturing facilities and personnel are located in a geographical area that is seismically active

Our corporate headquarters, primary manufacturing facilities and personnel are located in a geographical area that is known to be seismically active and prone to earthquakes. Should such a natural disaster occur, our ability to conduct our business could be severely restricted, and our business and assets, including the results of our research, development and manufacturing efforts, could be destroyed.

Risks Related To Our Industry

The market for our pharmaceutical product candidates is rapidly changing and competitive, and new products or technologies developed by others could impair our ability to grow our business and remain competitive

The pharmaceutical industry is subject to rapid and substantial technological change. Developments by others may render our product candidates under development or technologies noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

We may face competition from other companies in numerous industries including pharmaceuticals, medical devices and drug delivery. POSIDUR, TRANSDUR-Sufentanil, ELADUR, Relday, REMOXY and other ORADUR-based drug candidates, if approved, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, anti-psychotics, stimulants, implantable and external infusion pumps which can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Purdue Pharma, Knoll, Janssen, Medtronic, Endo, AstraZeneca, Arrow International, Tricumed, I-Flow (Kimberly-Clark), Cumberland Pharmaceuticals, Pacira, NeurogesX, Covidien, Shire, Johnson & Johnson, Eli Lilly, Pfizer, Pacira, Novartis and others. Our ORADUR-ADHD product candidates, if approved, will compete with currently marketed or approved products by Shire, Johnson & Johnson, UCB, Novartis, Noven, Celgene, Eli Lilly, Nextwave Pharmaceuticals (Pfizer) and others. Relday, if approved, will compete with currently marketed products by Johnson & Johnson, Eli Lilly, Astra Zeneca, Pfizer, Bristol-Myers Squibb and others. Numerous companies are applying significant resources and expertise to the problems of drug delivery and several of these are focusing or may focus on delivery of drugs to the intended site of action, including Alkermes, Pacira Pharmaceuticals, EpiCept, Innocoll, Nektar, I-Flow (Kimberly-Clark), NeurogesX, Flamel, Alexza, Cadence Pharmaceuticals, Hospira, Cumberland Pharmaceuticals, Egalet, Acura, Elite Pharmaceuticals, Phosphagenics, Intellipharmaceutics, Collegium Pharmaceutical and others. Some of these competitors may be addressing the same therapeutic areas or indications as we are. Our current and potential competitors may succeed in obtaining patent protection or commercializing products before us. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors financial, marketing, manufacturing and other resources.

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We are engaged in the development of novel therapeutic technologies. Our resources are limited and we may experience technical challenges inherent in such novel technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our product candidates. Our competitors may develop products that are safer, more effective or less costly than our product candidates and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our product candidates even if commercialized. Chronic and post-operative pain are currently being treated by oral medication, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices which will be competitive with our product candidates. These treatments are widely accepted in the medical community and have a long history of use. The established use of these competitive products may limit the potential for our product candidates to receive widespread acceptance if commercialized.

We could be exposed to significant product liability claims which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage

The testing, manufacture, marketing and sale of our product candidates involve an inherent risk that product liability claims will be asserted against us. Although we are insured against such risks up to an annual aggregate limit in connection with clinical trials and commercial sales of our product candidates, our present product liability insurance may be inadequate and may not fully cover the costs of any claim or any ultimate damages we might be required to pay. Product liability claims or other claims related to our product candidates, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant damages. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. In addition, product liability coverage may cease to be available in sufficient amounts or at an acceptable cost. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our product candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our product candidates.

Acceptance of our pharmaceutical product candidates in the marketplace is uncertain, and failure to achieve market acceptance will delay our ability to generate or grow revenues

Our future financial performance will depend upon the successful introduction and customer acceptance of our products in research and development, including REMOXY and other ORADUR-based drug candidates, POSIDUR, TRANSDUR-Sufentanil, ELADUR and Relday. Even if approved for marketing, our product candidates may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products, including oral medication, transdermal drug delivery products such as drug patches, or external or implantable drug delivery products; and
- pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations, hospital formularies and other health plan administrators.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our products. If we are unable to obtain regulatory approval, commercialize and market our future products when planned and achieve market acceptance, we will not achieve anticipated revenues.

If users of our products are unable to obtain adequate reimbursement from third-party payors, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and third-party collaborators and the availability of capital. For example, in certain foreign markets, pricing or profitability

of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care, and the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

The successful commercialization of our product candidates will depend in part on the extent to which appropriate reimbursement levels for the cost of our product candidates and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly limiting payments or reimbursement for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of

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organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may limit reimbursement or payment for our products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

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If we or our third-party collaborators are unable to train physicians to use our pharmaceutical product candidates to treat patients diseases or medical conditions, we may incur delays in market acceptance of our products

Broad use of our product candidates will require extensive training of numerous physicians on the proper and safe use of our product candidates. The time required to begin and complete training of physicians could delay introduction of our products and adversely affect market acceptance of our products. We or third parties selling our product candidates may be unable to rapidly train physicians in numbers sufficient to generate adequate demand for our product candidates. Any delay in training would materially delay the demand for our product candidates and harm our business and financial results. In addition, we may expend significant funds towards such training before any orders are placed for our products, which would increase our expenses and harm our financial results.

Potential new accounting pronouncements and legislative actions are likely to impact our future financial position or results of operations

Future changes in financial accounting standards may cause adverse, unexpected fluctuations in the timing of the recognition of revenues or expenses and may affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with frequency and may occur in the future and we may make changes in our accounting policies in the future. Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations, PCAOB pronouncements and NASDAQ rules, are creating uncertainty for companies such as ours and insurance, accounting and auditing costs are high as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Risks Related To Our Common Stock

Our stock price may not meet the minimum bid price for continued listing on the Nasdaq Global Market. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from The Nasdaq Global Market or if we are unable to transfer our listing to another stock market.

If the closing bid price of our common stock is below $1.00 for 30 consecutive trading days, our shares would no longer comply with the minimum closing bid price requirement for continued listing on the Nasdaq Global Market under Nasdaq Marketplace Rule 5450(a)(1). If this occurs, we expect that we would receive written notification from Nasdaq, and would have a 180-day period to regain compliance with Nasdaq s listing requirements by having the closing bid price of our common stock listed on Nasdaq be at least $1.00 for at least 10 consecutive trading days. If we do not regain compliance within this time period, we may transfer our common stock listing to The Nasdaq Capital Market, provided that the Company (i) meets the applicable market value of publicly held shares requirement for continued listing and all other applicable requirements for initial listing on The Nasdaq Capital Market (except for the closing bid price requirement) based on the Company s most recent public filings and market information and (ii) notifies Nasdaq of its intent to cure this deficiency. Following a transfer to The Nasdaq Capital Market, the Company would be afforded the remainder of an additional 180 calendar day grace period in order to regain compliance with the minimum closing bid price requirement of $1.00 per share under The Nasdaq Capital Market, unless it does not appear to NASDAQ that it would be possible for the Company to cure the deficiency.

If compliance is not demonstrated within the applicable compliance period, Nasdaq will notify the Company that its securities will be subject to delisting. The Company may appeal Nasdaq s determination to delist its securities to a Hearings Panel. During any appeal process, shares of the Company s common stock would continue to trade on the Nasdaq Global Market or Nasdaq Capital Market, as applicable.

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There can be no assurance that we will maintain or regain compliance with the requirements for listing our common stock on the Nasdaq Global Market or that our common stock would be eligible for transfer to the Nasdaq Capital Market and remain in compliance with the requirements for listing on that market. Delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Our operating history makes evaluating our stock difficult

Our quarterly and annual results of operations have historically fluctuated and we expect will continue to fluctuate for the foreseeable future. We believe that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies with no approved pharmaceutical products, particularly companies in new and rapidly evolving markets such as pharmaceuticals, drug delivery and biotechnology. To address these risks, we must, among other things, obtain regulatory approval for and commercialize our product candidates, which may not occur. We may not be successful in addressing these risks and difficulties. We may require additional funds to complete the development of our product candidates and to fund operating losses to be incurred in the next several years.

Investors may experience substantial dilution of their investment

Investors may experience dilution of their investment if we raise capital through the sale of additional equity securities or convertible debt securities or grant additional stock options to employees and consultants. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices for our common stock.

The price of our common stock may be volatile

The stock markets in general, and the markets for pharmaceutical stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock.

Price declines in our common stock could result from general market and economic conditions and a variety of other factors, including:

- failure of our third-party collaborators to successfully develop and commercialize the respective product candidates they are developing;
- adverse results (including adverse events or failure to demonstrate safety or efficacy) or delays in our clinical and non-clinical trials of POSIDUR, TRANSDUR-Sufentanil, ELADUR, REMOXY, our other ORADUR-based drug candidates, Relday or other product candidates;
- announcements of FDA non-approval of our product candidates, or delays in the FDA or other foreign regulatory agency review process;
- adverse actions taken by regulatory agencies or law enforcement agencies with respect to our product candidates, clinical trials, manufacturing processes or sales and marketing activities, or those of our third party collaborators;
- announcements of technological innovations, patents, product approvals or new products by our competitors;
- regulatory, judicial and patent developments in the United States and foreign countries;

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any lawsuit involving us or our product candidates including intellectual property infringement or product liability suits;

announcements concerning our competitors, or the biotechnology or pharmaceutical industries in general;

developments concerning our strategic alliances or acquisitions;

actual or anticipated variations in our operating results;

changes in recommendations by securities analysts or lack of analyst coverage;

deviations in our operating results from the estimates of analysts;

sales of our common stock by our executive officers or directors or sales of substantial amounts of common stock by others;

potential failure to meet continuing listing standards from The NASDAQ Global Market;

loss or disruption of facilities due to natural disasters;

changes in accounting principles; or

loss of any of our key scientific or management personnel.

The market price of our common stock may fluctuate significantly in response to factors which are beyond our control. The stock market in general has recently experienced extreme price and volume fluctuations. In addition, the market prices of securities of technology and pharmaceutical companies have also been extremely volatile, and have experienced fluctuations that often have been unrelated or disproportionate to the operating performance of these companies. These broad market fluctuations could result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of our common stock.

In the past, following periods of volatility in the market price of a particular company s securities, litigation has often been brought against that company. If litigation of this type is brought against us, it could be extremely expensive and divert management s attention and our company s resources.

We have broad discretion over the use of our cash and investments, and their investment may not always yield a favorable return

Our management has broad discretion over how our cash and investments are used and may from time to time invest in ways with which our stockholders may not agree and that do not yield favorable returns.

Executive officers, directors and principal stockholders have substantial control over us, which could delay or prevent a change in our corporate control favored by our other stockholders

Our directors, executive officers and principal stockholders, together with their affiliates, have substantial control over us. The interests of these stockholders may differ from the interests of other stockholders. As a result, these stockholders, if acting together, could have the ability to exercise control over all corporate actions requiring stockholder approval irrespective of how our other stockholders may vote, including:

the election of directors;

the amendment of charter documents;

the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets; or

the defeat of any non-negotiated takeover attempt that might otherwise benefit the public stockholders.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that could discourage another company from acquiring us.

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Provisions of Delaware law, our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

authorizing the issuance of blank check preferred stock without any need for action by stockholders;

providing for a classified board of directors with staggered terms;

requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;

eliminating the ability of stockholders to call special meetings of stockholders;

prohibiting stockholder action by written consent; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds
None

Item 3. Defaults Upon Senior Securities
None

Item 4. Mine Safety Disclosures
None

Item 5. Other Information
None

Item 6. Exhibits

10.34**	Development and License Agreement between the Company, Southern BioSystems, Inc., an Alabama corporation and wholly-owned subsidiary of the Company (now merged into the Company), and Pain Therapeutics, Inc. dated as of December 19, 2002 (incorporated by reference to Exhibit 10.34 to our Annual Report on Form 10-K (File No. 000-31615) filed on March 14, 2003).
10.70	Amendment dated March 18, 2013 to Development and License Agreement dated July 11, 2011 between the Company and Zogenix, Inc.
31.1	Rule 13a-14(a) Section 302 Certification of James E. Brown.
31.2	Rule 13a-14(a) Section 302 Certification of Matthew J. Hogan.
32.1	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of James E. Brown.
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101.SCH	XBRL Taxonomy Extension Schema Document+
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document+
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document+
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document+

** Confidential treatment previously granted with respect to certain portions of this Exhibit.
Refiled with additional disclosure previously treated as confidential.
Confidential treatment has been requested with respect to portions of this exhibit. The redacted information has been filed separately with the SEC.

+ These interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DURECT CORPORATION

By: /S/ JAMES E. BROWN
James E. Brown

Chief Executive Officer

Date: May 3, 2013

By: /S/ MATTHEW J. HOGAN
Matthew J. Hogan

Chief Financial Officer and Principal Accounting Officer

Date: May 3, 2013

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