DURECT CORP
Form 10-Q
May 10, 2010
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2010

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.)**

2 Results Way

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 ¨ 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, 2010, there were 86,782,778 shares of the registrant s Common Stock outstanding.

Table of Contents

INDEX

		Page
	PART I. FINANCIAL INFORMATION	
Item 1.	Condensed Financial Statements (Unaudited)	3
	Condensed Balance Sheets *As of March 31, 2010 and December 31, 2009*	3
	Condensed Statements of Operations *For the three months ended March 31, 2010 and 2009*	4
	Condensed Statements of Cash Flows *For the three months ended March 31, 2010 and 2009*	5
	Notes to Condensed Financial Statements	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	17
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	29
Item 4.	Controls and Procedures	29
	PART II. OTHER INFORMATION	
Item 1.	Legal Proceedings	30
Item 1A.	Risk Factors	30
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	46
Item 3.	Defaults Upon Senior Securities	46
Item 4.	[Removed and Reserved]	46
Item 5.	Other Information	46
Item 6.	Exhibits	46
	(a) Exhibits	
Signatures		47

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

	March 31, 2010 (unaudited)	December 31, 2009 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,529	$ 8,287
Short-term investments	31,827	32,834
Short-term restricted investments	66	
Accounts receivable (net of allowances of $127 and $103 at March 31, 2010 and December 31, 2009, respectively)	3,603	1,700
Inventories	2,651	2,799
Prepaid expenses and other current assets	1,712	1,433
Total current assets	43,388	47,053
Property and equipment (net of accumulated depreciation of $20,861 and $20,190 at March 31, 2010 and December 31, 2009, respectively)	3,158	3,808
Goodwill	6,399	6,399
Intangible assets, net	96	108
Long-term restricted investments	366	431
Other long-term assets	344	352
Total assets	$ 53,751	$ 58,151
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,018	$ 1,019
Accrued liabilities	5,246	5,337
Contract research liability	1,421	990
Deferred revenue, current portion	4,530	4,703
Other short-term liabilities	220	208
Total current liabilities	12,435	12,257
Deferred revenue, non-current portion	16,430	17,543
Other long-term liabilities	447	508
Commitments		
Stockholders equity:		
Common stock	8	8
Additional paid-in capital	344,932	341,705
Accumulated other comprehensive income	5	10
Accumulated deficit	(320,506)	(313,880)
Stockholders equity	24,439	27,843

Total liabilities and stockholders equity	$ 53,751	$ 58,151

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

Table of Contents

DURECT CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	Three months ended March 31,	
	2010	**2009**
Collaborative research and development and other revenue	$ 3,816	$ 3,745
Product revenue, net	3,850	2,415
Total revenues	7,666	6,160
Operating expenses:		
Cost of product revenues (1)	1,378	824
Research and development (1)	9,421	9,903
Selling, general and administrative (1)	3,502	4,257
Total operating expenses	14,301	14,984
Loss from operations	(6,635)	(8,824)
Other income (expense):		
Interest and other income	11	179
Interest expense	(2)	(11)
Net other income	9	168
Net loss	$ (6,626)	$ (8,656)
Net loss per share, basic and diluted	$ (0.08)	$ (0.11)
Shares used in computing basic and diluted net loss per share	86,756	82,023

(1) Includes stock-based compensation related to the following:

Cost of product revenues	$ 84	$ 78
Research and development	1,277	2,281
Selling, general and administrative	669	1,171
Total stock-based compensation	$ 2,030	$ 3,530

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

Table of Contents

DURECT CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Three months ended March 31,	
	2010	**2009**
Cash flows from operating activities		
Net loss	$ (6,626)	$ (8,656)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	683	596
Stock-based compensation	2,030	3,530
Changes in assets and liabilities:		
Accounts receivable	(1,903)	663
Inventories	137	894
Prepaid expenses and other assets	(271)	(1,297)
Accounts payable	(1)	(306)
Accrued and other liabilities	1,068	(421)
Contract research liability	431	(350)
Deferred revenue	(1,286)	(277)
Total adjustments	888	3,032
Net cash used in operating activities	(5,738)	(5,624)
Cash flows from investing activities		
Purchases of property and equipment	(21)	(48)
Purchases of available-for-sale securities	(12,398)	(14,083)
Proceeds from maturities of available-for-sale securities	13,400	12,590
Proceeds from sales of available-for-sale securities		1,154
Net cash provided by (used in) investing activities	981	(387)
Cash flows from financing activities		
Payments on equipment financing obligations	(12)	(10)
Net proceeds from issuances of common stock through exercise of options	11	39
Net cash (used in) provided by financing activities	(1)	29
Net decrease in cash and cash equivalents	(4,758)	(5,982)
Cash and cash equivalents, beginning of the period	8,287	29,445
Cash and cash equivalents, end of the period	$ 3,529	$ 23,463

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

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Nature of Operations

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

Basis of Presentation

The accompanying unaudited financial statements include the accounts of the Company. These financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and therefore, do not include all the information and footnotes necessary for a complete presentation of the Company s results of operations, financial position and cash flows in conformity with U.S. generally accepted accounting principles (U.S. GAAP). The unaudited financial statements reflect all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair presentation of the financial position at March 31, 2010, the operating results for the three months ended March 31, 2010 and 2009, and cash flows for the three months ended March 31, 2010 and 2009. The balance sheet as of December 31, 2009 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, 2009 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.

Inventories consisted of the following (in thousands):

	March 31, 2010 (unaudited)	December 31, 2009
Raw materials	$ 533	$ 516
Work in process	591	690
Finished goods	1,527	1,593
Total inventories	$ 2,651	$ 2,799

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 up-front 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 research and development services. The Company evaluates whether there is

stand-alone value for the delivered elements and objective and reliable evidence of fair value to allocate revenue to each element in multiple element agreements. When the delivered element does not have stand-alone value or there is insufficient evidence of fair value for the undelivered element(s), the Company recognizes the consideration for the combined unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is generally ratably over the longest period of involvement. Returns or credits related to the sale of products have not had a material impact on our revenues or net loss.

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

Upfront payments received upon execution of collaborative agreements are recorded as deferred revenue and recognized as collaborative research and development revenue based on a straight-line basis over the period of the Company s continuing involvement with the third-party collaborator pursuant to the applicable agreement. Such period generally represents the research and development period set forth in the work plan defined in the respective agreements between the Company and its third-party collaborators.

Research and development revenue related to services performed under the collaborative arrangements with the Company s third-party collaborators is recognized as the related research and development services are performed. These research payments received under each respective agreement are not refundable and are generally based on reimbursement of qualified expenses, as defined in the agreements. Research and development expenses under the collaborative research and development agreements generally approximate or exceed the revenue recognized under such agreements over the term of the respective agreements. Deferred revenue may result when the Company does not expend the required level of effort during a specific period in comparison to funds received under the respective agreement. For joint control and funding development activities, the Company records reimbursements receivable from the joint venture party as a reduction in research and development expense.

Milestone payments under collaborative arrangements are recognized as collaborative research and development revenue upon achievement of the milestone events, which represent the culmination of the earnings process related to that milestone as defined in the agreement. Milestone payments are triggered either by the results of our research and development efforts or by events external to us, such as regulatory approval to market a product or the achievement of specified sales levels by a third-party collaborator. As such, the milestones are substantially at risk at the inception of the collaboration agreement, and revenue is only recognized upon the achievement of a milestone event if the Company has no future performance obligations related to that milestone payment.

The Company recognizes upfront fees on a straight-line basis over the period in which the Company has continuing involvement with the third-party collaborator pursuant to the applicable agreement. Such period generally represents the research and development period set forth in the work plan under each collaboration agreement between the Company and its third-party collaborator. 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.

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,	
	2010	2009
Collaborator		
King Pharmaceuticals, Inc. (King)(1)	$ 2,575	$ 1,924
Pain Therapeutics, Inc. (Pain Therapeutics)	701	276
Nycomed Danmark, APS (Nycomed)(2)	309	381
Endo Pharmaceuticals, Inc. (Endo)(3)		985
Others	231	179
Total collaborative research and development and other revenue	$ 3,816	$ 3,745

Notes:

(1) Amounts related to the ratable recognition of upfront fees were $804,000 and $1.0 million for the three months ended March 31, 2010 and 2009 respectively.

(2) Amounts related to the ratable recognition of upfront fees were $309,000 and $381,000 for the three months ended March 31, 2010 and 2009 respectively. Research and development expenses incurred by us in conjunction with the Nycomed collaboration and reimbursable by Nycomed are recorded as a reduction to total research and development expense.

(3) Amounts related to the ratable recognition of upfront fees were zero and $875,000 for the three months ended March 31, 2010 and 2009 respectively. The Company s agreement with Endo was terminated effective August 26, 2009.

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

Research and Development Expenses

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 costs are expensed as incurred. Research and development costs paid to third parties under sponsored research agreements are recognized as the related services are performed, generally ratably over the period of service. In addition, reimbursements by Nycomed for research and development expenses incurred by the Company are recorded as a reduction to research and development expenses. Research and development expenses incurred by Nycomed and reimbursed by the Company are recorded as additional research and development expenses.

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

	Three months ended March 31,	
	2010	2009
POSIDUR (1)	$ 4,595	$ 3,488
ELADUR	1,286	1,483
Remoxy and other ORADUR-based opioid products licensed to Pain Therapeutics	850	458
Biologics Programs	247	657
ORADUR-ADHD	238	979
TRANSDUR-Sufentanil	175	418
Others	2,030	2,420
Total research and development expenses (2)	$ 9,421	$ 9,903

(1) In the three months ended March 31, 2010 and 2009, research and development expenses for POSIDUR incurred by the Company but reimbursable by Nycomed under the terms of the Company s agreement with Nycomed were $523,000 and $1.1 million, respectively, which were accounted for as a reduction of research and development expenses. In the three months ended March 31, 2010 and 2009, research and development expenses for POSIDUR incurred by Nycomed but reimbursable by the Company under the terms of the Company s agreement with Nycomed were $820,000 and $945,000, respectively, which were accounted for as additional research and development expenses. Please see Note 2 Strategic Agreements in the condensed financial statements for more details about the Company s agreement with Nycomed.

(2) Includes stock-based compensation expenses of $1.3 million and $2.3 million for the three months ended March 31, 2010 and 2009, respectively.

Comprehensive Loss

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

	Three months ended March 31,	
	2010	2009
Net loss	$ (6,626)	$ (8,656)

Net change in unrealized gain on available-for-sale investments, net of tax	(5)	(75)
Comprehensive loss	$ (6,631)	$ (8,731)

Accumulated other comprehensive income as of March 31, 2010 and December 31, 2009 is entirely comprised of net unrealized gains, net of taxes.

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding. Diluted net 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 year, if dilutive, using the treasury stock method for options and warrants.

	Three months ended March 31,	
	2010	2009
	(In thousands)	
Outstanding dilutive securities not included in diluted net loss per share		
Options to purchase common stock	19,243	16,073
Warrants	1	1
Total	19,244	16,074

Recent Accounting Pronouncements

In September 2009, the FASB issued Update No. 2009-13, *Multiple-Deliverable Revenue Arrangements a consensus of the FASB Emerging Issues Task Force* (ASU 2009-13). It updates the existing multiple-element revenue arrangements guidance currently included under ASC 605-25, which originated primarily from the guidance in EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21). The revised guidance primarily provides two significant changes: (1) eliminates the need for objective and reliable evidence of the fair value for the undelivered element in order for a delivered item to be treated as a separate unit of accounting, and (2) eliminates the residual method to allocate the arrangement consideration. In addition, the guidance also expands the disclosure requirements for revenue recognition. ASU 2009-13 will be effective for the first annual reporting period beginning on or after June 15, 2010, with early adoption permitted provided that the revised guidance is retroactively applied to the beginning of the year of adoption. The Company expects to adopt ASU 2009-13 prospectively as of January 1, 2011. The Company is currently assessing the future impact of this new accounting update to its financial statements.

In March of 2010, Accounting Standards Codification Topic 605, Revenue Recognition (ASC 605) was amended to define a milestone and clarify that the milestone method of revenue recognition is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, a company can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The Company will adopt this guidance in the third quarter of 2010 on a prospective basis. The Company is assessing the impact of this guidance on its results of operations and financial condition.

Note 2. Strategic Agreements

Agreement with Alpharma Ireland Limited, an affiliate of Alpharma Inc. (Alpharma) (acquired by King)

Effective October 2008, the Company and Alpharma entered into a development and license agreement granting Alpharma the exclusive worldwide rights to develop and commercialize ELADUR, DURECT s investigational transdermal bupivacaine patch. As a result of the acquisition of Alpharma by King in December 2008, King has assumed all the rights and obligations of Alpharma under the agreement.

Under the terms of the agreement, upon closing of the transaction, Alpharma paid the Company an upfront license fee of $20.0 million, with possible additional payments of up to $93.0 million upon the achievement of predefined development and regulatory milestones spread over multiple clinical indications and geographical territories as well as possible additional payments of up to $150.0 million in sales-based milestones. If ELADUR is commercialized, the Company would also receive royalties on product sales. Alpharma will control and fund further

development of the program. The term of the agreement will continue on a jurisdiction-by-jurisdiction basis until the later of fifteen (15) years from the date of first commercial sale of ELADUR or the expiration of patent coverage or data exclusivity in such jurisdiction. During the term of the agreement, subject to specified conditions, neither party nor their affiliates may develop or commercialize a transdermal patch containing bupivacaine. Upon expiration of the term of the agreement, the rights and licenses granted to Alpharma shall convert to fully paid-up, non-royalty bearing, perpetual rights and licenses. The agreement provides each party with specified termination rights, including the right of Alpharma to terminate at any time without cause and each party to terminate the agreement upon material breach of the agreement by the other party. The agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties and indemnities.

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

For the three months ended March 31, 2010 and 2009, respectively, the Company recognized $804,000 and $1.0 million as collaborative research and development revenue from the ratable recognition of the $20.0 million upfront fee received, and $960,000 and $911,000 as collaborative research and development revenue from research expenses that are qualified for reimbursement by Alpharma. The Company s estimate of the remaining term of our continuing involvement was modified in the second quarter of 2009 as a result of an updated development plan provided by King for ELADUR. Total collaborative research and development revenue recognized under this arrangement was $1.8 million and $1.9 million for the three months ended March 31, 2010 and 2009, respectively. The cumulative aggregate payments received by the Company as of March 31, 2010 were $25.7 million under this agreement.

Agreement with Nycomed

In November 2006, the Company entered into a development and license agreement with Nycomed, and this agreement was amended in February 2010. Under the terms of the agreement, the Company licensed to Nycomed the exclusive commercialization rights to POSIDUR for the European Union (E.U.) and certain other countries. Nycomed paid an upfront license fee of $14.0 million in 2006 and a milestone payment of $8.0 million in 2007, with future potential additional milestone payments of up to $181.0 million upon achievement of defined development, regulatory and sales milestones. Prior to the February 2010 amendment, the agreement provided for the Company and Nycomed to jointly directing and equally funding with Nycomed a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the E.U. After the amendment, DURECT now has final decision-making authority over clinical trials intended for the U.S. registration of POSIDUR and Nycomed now has decision-making authority over clinical trials for the E.U. and other countries licensed to it. DURECT will have funding responsibility for all current and future clinical trials intended for U.S. registration of POSIDUR and, commencing April 1, 2010, Nycomed will have sole funding responsibility for all clinical trials intended for E.U. registration of POSIDUR. The final decision making authority and financial responsibility for the remainder of the development activities, such as the non-clinical and CMC activities, will be jointly managed and funded by DURECT and Nycomed. In addition, the Company will manufacture and supply the product to Nycomed for commercial sale in the territory licensed to Nycomed. Nycomed will pay the Company blended royalties on sales in the defined territory of 15-40% depending on annual sales, as well as a manufacturing markup. The Company retains full commercial rights to POSIDUR in the U.S., Canada, Japan and other countries. The agreement shall continue in effect until terminated. The agreement provides each party with specified termination rights, including the right of each party to terminate the agreement upon material breach of the agreement by the other party. In addition, Nycomed shall have the right to terminate the agreement after expiration of patents covering POSIDUR in all major market countries in the E.U. and for adverse product events, and within specified periods after clinical trials of POSIDUR.

In contrast to the Company s other collaborations, because the Company and Nycomed jointly control, fund, and benefit from the development of POSIDUR, the Company does not recognize revenue from the reimbursement of qualified research expenses by Nycomed. Rather, the Company records research expense equal to its share of the joint expenses incurred under the product development plan. Research and development expenses for POSIDUR incurred by us but reimbursable by Nycomed under the terms of our agreement with Nycomed were $523,000 and $1.1 million for the three months ended March 31, 2010 and 2009, respectively, which were accounted for as a reduction of research and development expenses. Research and development expenses for POSIDUR incurred by Nycomed but reimbursable by us under the terms of our agreement with Nycomed were $820,000 and $945,000 for the three months ended March 31, 2010 and 2009, respectively, and were accounted for as additional research and development expenses. Both parties bear 50% of the agreed upon expenses under the collaboration agreement for POSIDUR. The Company recognized $309,000 and $381,000 for the three months ended March 31, 2010 and 2009, respectively, as collaborative research and development revenue from the ratable recognition of the $14.0 million upfront fee received in 2006. The Company s estimate of the remaining term of its continuing involvement was modified in the first and fourth quarter of 2009 as a result of an updated development plan for POSIDUR in Europe. In addition, the Company recognized an additional $8.0 million as collaborative research and development revenue, triggered by the achievement of a clinical development milestone under its Nycomed collaboration in 2007. The cumulative aggregate payments received by the Company from Nycomed as of March 31, 2010 were $34.8 million under this agreement. In addition, the cumulative aggregate payments paid by the Company to Nycomed were $7.1 million as of March 31, 2010.

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

Agreement with Endo Pharmaceuticals

On March 10, 2005, the Company entered into a license agreement with Endo under which the Company granted to Endo the exclusive right to develop, market and commercialize TRANSDUR-Sufentanil in the U.S. and Canada. The Company received an initial payment of $10.0 million in connection with the execution of the agreement. The license agreement was terminated by Endo effective August 26, 2009.

The $10.0 million upfront fee is recognized as revenue ratably over the term of the Company s obliged continuing involvement with Endo with respect to TRANSDUR-Sufentanil. The term of the continuing involvement had been estimated based on the product development plan pursuant to the agreement. The Company s estimate of the remaining term of its continuing involvement was modified in the fourth quarter of 2008 as a result of Endo s termination notice received by the Company in February 2009.

The Company recognized zero and $875,000, respectively, as collaborative research and development revenue from the ratable recognition of the $10.0 million upfront fee for the three months ended March 31, 2010 and 2009. Total collaborative research and development revenue recognized under this arrangement was zero and $985,000 for the three months ended March 31, 2010 and 2009, respectively. The cumulative aggregate payments received by the Company as of March 31, 2010 were $21.5 million under this agreement.

Agreement with Pain Therapeutics

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. The agreement also provides Pain Therapeutics with the exclusive right to commercialize products developed under the agreement on a worldwide basis. In connection with the execution of the agreement, Pain Therapeutics paid the Company upfront fees of $900,000 in December 2002 and $100,000 in October 2003. In December 2005, the Company amended its agreement with Pain Therapeutics in order to specify its obligations with respect to the supply of key excipients for use in the licensed products. Under the agreement, as amended, the Company is responsible for formulation development, supply of selected key excipients used in the manufacture of licensed products and other specified tasks. Under the agreement with Pain Therapeutics, subject to and upon the achievement of predetermined development and regulatory milestones for the four drug candidates currently in development, the Company is entitled to receive milestone payments of up to $9.3 million in the aggregate. As of December 31, 2009, the Company had received $1.7 million in cumulative milestone payments. In addition, if commercialized, the Company will receive royalties for Remoxy and other licensed products which do not contain an opioid antagonist of between 6.0% to 11.5% of net sales of the product depending on sales volume. This agreement can be terminated by either party for material breach by the other party and by Pain Therapeutics without cause. Under the agreement, Pain Therapeutics reimburses the Company for qualified expenses incurred by the Company in connection with the development program. The Company recognizes collaborative research and development revenue related to research and development activities for Remoxy and other development programs based on reimbursement of qualified expenses as defined in the collaborative agreement and related amendment with Pain Therapeutics. Total collaborative research and development revenue recognized under the agreement with Pain Therapeutics was $701,000 and $276,000 for the three months ended March 31, 2010 and 2009, respectively. The cumulative aggregate payments received by the Company as of March 31, 2010 were $31.9 million under this 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, but with King substituted in lieu of Pain Therapeutics with respect to interactions with the Company in the Company s performance of those activities including the obligation to pay the Company with respect to all Remoxy-related costs incurred by the Company. Total collaborative research and development revenue recognized for Remoxy-related work performed by the Company for King was $810,000 and zero for the three months ended March 31, 2010 and 2009, 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 King as of March 31, 2010 were $1.2 million under this agreement.

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

Long Term Supply Agreement with King

During 2008, the Company began to manufacture commercial lots of certain key excipients that are included in Remoxy to meet the anticipated requirements for these components. In addition, during the second, third and fourth quarters of 2008 and the first quarter of 2009, the Company made shipments of these materials to meet the production requirements of King, which has rights to commercialize Remoxy upon approval by the FDA. During these periods, all product revenue and associated cost of goods sold was deferred pending the establishment of definitive final terms and conditions even though cash receipts and expenditures occurred during these periods.

In August 2009, the Company signed an exclusive long term excipient supply agreement with respect to Remoxy with King. 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 the third quarter of 2009, the Company recognized $3.0 million of product revenue and $2.0 million of cost of goods sold related to its past shipments to King upon execution of the long term supply agreement at which point all criteria of revenue recognition were met.

In the three months ended March 31, 2010, the Company recognized approximately $551,000 of product revenue for shipments made in 2008 and 2009 related to a price settlement after all criteria of revenue recognition were met. This adjustment represents the additional manufacturing cost incurred by the Company and certain mark up for the goods produced and shipped in 2008 and 2009 pursuant to the long term excipient supply agreement. In addition, the Company also recognized approximately $410,000 of product revenue related to the shipment of another excipient that is included in Remoxy upon shipment to King in the three months ended March 31, 2010. Total revenue recognized related to these excipients was $961,000 in the three months ended March 31, 2010 and the associated costs of goods sold was $315,000 compared to zero for the corresponding period in 2009. Revenue attributable to shipments of these key components aggregating $1.7 million and cost of goods sold aggregating $1.5 million in the three months ended March 31, 2009 was recognized upon the execution of a final supply agreement with King in the third quarter of 2009 rather than the first quarter of 2009.

The term of the agreement commenced on August 5, 2009 and will continue in effect until the earlier of the expiration of all licenses granted under the development and license agreement between the Company and Pain Therapeutics or the termination or expiration of the 2005 development and license agreement between Pain Therapeutics and King, unless the agreement is terminated earlier in accordance with its terms. The agreement provides each party with specified termination rights, which include, but are not limited to, the right of King to terminate the agreement in the event that governmental action requires the withdrawal of Remoxy from all countries in the territory or results in the withdrawal of required manufacturing approvals, or upon a change of control of the Company, in which case termination will be effective one year after notice by King. The Company may terminate the agreement if the Company is unable to procure suitable and sufficient quantities of certain raw materials required to produce the excipient ingredients. Each party may terminate the agreement upon material breach of the agreement by, or the bankruptcy or insolvency of, the other party, in each case subject to a cure period. The agreement further specifies the rights and obligations of the Company and King with respect to plant allocation, adding additional production capacity and sourcing of raw materials, as well as other terms and conditions customary for this type of agreement, including those regarding forecasting, purchasing, invoicing, representations, warranties and indemnities.

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

Note 3. Fair Value Measurements

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 following table sets forth the fair-value of the Company s financial assets that were measured at fair value on a recurring basis as of March 31, 2010 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	$ 880	$	$	$ 880
Certificates of deposit		432		432
Commercial paper		7,497		7,497
Corporate debt		1,504		1,504
U.S. Government agencies		24,725		24,725
Total	$ 880	$ 34,158	$	$ 35,038

The following table sets forth the fair value of our financial assets that were measured at fair value on a recurring basis as of December 31, 2009 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	$ 4,157	$	$	$ 4,157
Certificates of deposit		431		431
Commercial paper		9,546		9,546
Corporate debt		2,838		2,838
U.S. Government agencies		22,800		22,800
Total	$ 4,157	$ 35,615	$	$ 39,772

The fair value of the Level 2 assets is estimated using pricing models using current observable market information for similar securities. There is a small degree of variation in the pricing sources for these securities, however the potential differences in the estimate of fair value for the Company s available-for-sale securities are insignificant.

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

The following is a summary of available-for-sale securities as of March 31, 2010 and December 31, 2009 (in thousands):

	March 31, 2010			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 880	$	$	$ 880
Certificates of deposit	432			432
Commercial paper	7,497			7,497
Corporate debts	1,503	1		1,504
U.S. Government agencies	24,722	7	(4)	24,725
	$ 35,034	$ 8	$ (4)	$ 35,038
Reported as:				
Cash and cash equivalents	$ 2,779	$	$	$ 2,779
Short-term investments	31,823	8	(4)	31,827
Short-term restricted investments	66			66
Long-term restricted investments	366			366
	$ 35,034	$ 8	$ (4)	$ 35,038

	December 31, 2009			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 4,157	$	$	$ 4,157
Certificates of deposit	431			431
Commercial paper	9,545	1		9,546
Corporate debt	2,833	5		2,838
U.S. Government agencies	22,796	10	(6)	22,800
	$ 39,762	$ 16	$ (6)	$ 39,772
Reported as:				
Cash and cash equivalents	$ 6,507	$	$	$ 6,507
Short-term investments	32,824	16	(6)	32,834
Long-term restricted investments	431			431
	$ 39,762	$ 16	$ (6)	$ 39,772

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

As of March 31, 2010, all available-for-sale debt securities had a remaining maturity of less than one year. During the three months ended March 31, 2010 and 2009, realized gains or losses recognized on the sale of investments were not material.

The following is a summary of unrealized losses for available-for-sale securities at March 31, 2010 (in thousands):

	Unrealized Loss for Less than 12 Months	
	Fair Value	Unrealized Loss
U.S. Government agencies	$ 15,762	$ (4)
	$ 15,762	$ (4)

The following is a summary of unrealized losses for available-for-sale securities at December 31, 2009 (in thousands):

	Unrealized Loss for Less than 12 Months	
	Fair Value	Unrealized Loss
U.S. Government agencies	$ 13,628	$ (6)
	$ 13,628	$ (6)

There were no securities that have had an unrealized loss for more than 12 months as of March 31, 2010 and December 31, 2009.

As of March 31, 2010, 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.

Note 4. Stock-Based Compensation

As of March 31, 2010, the Company has four stock-based employee compensation plans. The employee stock-based compensation cost that has been included in the statements of operations was $2.0 million and $3.5 million for the three months ended March 31, 2010 and 2009, respectively.

As of March 31, 2010 and December 31, 2009, $50,000 and $60,000, respectively, of stock-based compensation cost was capitalized in inventory on the Company s balance sheets.

Table of Contents

DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS (Continued)

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, 2010 and 2009:

	Stock Options Three months ended March 31,		Employee Stock Purchase Plan Three months ended March 31,	
	2010	2009	2010	2009
Risk-free rate	2.7-2.9%	2.0-2.3%	0.2-2.4%	1.1-4.0%
Expected dividend yield				
Expected life of option (in years)	6	6	1.25	1.25
Volatility	82%	84-87%	57-150%	51-95%
Forfeiture rate	7.0%	6.1%		

Table of Contents

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

This Management s Discussion and Analysis of Financial Condition and Results of Operations for the three months ended March 31, 2010 and 2009 should be read in conjunction with our annual report on Form 10-K for the year ended December 31, 2009 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. 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:

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

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

our expectations regarding the 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, protect intellectual property and manufacture product;

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, E.U. and other government regulation on our business;

the impact of potential Risk Evaluation and Mitigation Strategies our business;

uncertainties associated with obtaining and protecting patents and other intellectual property rights;

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 in focused specialty areas;

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 systems for at least twelve months and our expectations regarding our ability to achieve profitability;

sufficiency of our cash resources, anticipated capital requirements 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.

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 of this Quarterly Report on Form 10-Q and the 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.

Table of Contents

Overview

We are an emerging specialty pharmaceutical company focused on the development of pharmaceutical systems based on proprietary drug delivery technology platforms. We are developing and commercializing pharmaceutical systems that will deliver the right drug to the right place in the right amount at the right time to treat chronic or episodic diseases and conditions. By integrating chemistry and engineering advancements, we seek to achieve what drugs or devices alone cannot. Our pharmaceutical systems enable optimized therapy for a given disease or patient population by controlling the rate and duration of drug administration and providing sustained drug delivery.

In addition to developing our own proprietary products, we enter into strategic collaborations with pharmaceutical companies to develop and commercialize proprietary and enhanced pharmaceutical products based on our technologies. We have seven disclosed on-going product candidates in development. Summary descriptions of such these product candidates and related activities since December 31, 2009 are below. 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, 2009 or in Note 2 above.

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 can be formulated for systemic or local administration of drugs via the parenteral (i.e., injectable) route. 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 January 2010, we announced that we had commenced BESST (Bupivacaine Effectiveness and Safety in SABER Trial), which is intended to be the pivotal Phase III clinical trial in the U.S. BESST is an international, multi-center, randomized, double-blind, controlled trial evaluating the safety, efficacy, and pharmacokinetics of POSIDUR in approximately 300 patients undergoing a variety of general abdominal surgical procedures. Eligible patients will be randomly assigned to one of three cohorts:

Cohort 1: An active comparator cohort in which patients are randomized to receive either POSIDUR 5.0 mL or commercially available Bupivacaine HCl solution after laparotomy.

Cohort 2: An active comparator cohort in which patients are randomized to receive either POSIDUR 5.0 mL or commercially available Bupivacaine HCl solution after laparoscopic cholecystectomy.

Cohort 3: A double blind, placebo controlled cohort in which patients are randomized to receive either POSIDUR 5.0 mL or SABER-Placebo after laparoscopically-assisted colectomy.

Efficacy evaluation in the BESST trial will encompass a number of parameters. The two co-primary efficacy endpoints for Cohort 3 will be 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. An adaptive feature of BESST allows for increasing the patient sample size in Cohort 3 based on pooled and blinded data. The purpose of Cohorts 1 and 2 is to give us additional experience with the use of POSIDUR in a broader group of surgeries and patients.

Nycomed is conducting Phase IIb studies in hysterectomy patients and shoulder surgery patients. These trials are being conducted by Nycomed in a different manner than U.S. studies and are designed to be suitable for European regulatory approval purposes.

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

Table of Contents

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.

During 2008, we began to manufacture commercial lots of certain key excipients that are included in Remoxy to meet the anticipated requirements for these components. In the three months ended March 31, 2010, the Company recognized approximately $551,000 of product revenue for shipments made in 2008 and 2009 related to a price settlement after all criteria of revenue recognition were met. This adjustment reflects a final accounting of actual manufacturing costs for the goods produced and shipped in 2008 and 2009 pursuant to the long term excipient supply agreement. In addition, the Company also recognized approximately $410,000 of product revenue related to the shipment of another excipient that is included in Remoxy upon shipment to King in the three months ended March 31, 2010. Total revenue recognized related to these excipients was $961,000 in the three months ended March 31, 2010 and the associated cost of goods sold was $315,000 compared to zero for both revenue and cost of goods sold for the corresponding period in 2009. Revenue attributable to shipments of these key components aggregating $1.7 million and cost of goods sold aggregating $1.5 million in the three months ended March 31, 2009 was recognized upon the execution of a final supply agreement with King in the third quarter of 2009 rather than the first quarter of 2009.

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. We are now in discussions with multiple parties regarding licensing of this program.

Table of Contents

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.

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 are now controlled by King.

In April 2010, King commenced a Phase IIb clinical trial to evaluate ELADUR for the treatment of chronic low back pain. This Phase IIb trial is a 12-week, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of ELADUR in patients with chronic low back pain. King expects to enroll approximately 260 patients in the study.

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. We anticipate commencing Phase I studies in 2010.

Other Programs

Biologics Programs

The proteins 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 digested before they can have an effect; if given by injection, they may be destroyed by the body s natural processes before they can reach their intended sites of action. The body s natural elimination processes require frequent, high dose injections that may result in unwanted side effects. As a result, the development of biotechnology molecules for the treatment of human diseases has been limited, and advanced drug delivery systems such as we possess are required to realize the full potential of many of these protein and peptide drugs. We have active programs underway to apply our drug delivery systems to various biotechnology 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 (CNS), including schizophrenia and cardiovascular disease, including congestive heart failure. 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.

Table of Contents

Because we consider our core business to be developing and commercializing pharmaceutical systems, 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.

Operating Results

Since our inception in 1998, we have had a history of operating losses. At March 31, 2010, we had an accumulated deficit of $320.5 million and our net losses were $6.6 million for the three months ended March 31, 2010. Our net losses were $30.3 million, $43.9 million and $24.3 million for the years ended December 31, 2009, 2008 and 2007, 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 increase in the near future as we expect to continue to expand our clinical trials, nonclinical studies and other research and development activities. We expect selling, general and administrative expenses to remain comparable in the near future. We do not anticipate meaningful revenues from our pharmaceutical systems, 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

General

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.

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 our part exists, the price is fixed or determinable and the collectibility of the amounts owed is reasonably assured. We enter into license and collaboration agreements under which we may receive up-front license fees, research funding and contingent milestone payments and royalties. Our deliverables under these arrangements typically consist of intellectual property rights and research and development services. We evaluate whether there is stand-alone value for the delivered elements and objective and reliable evidence of fair value for the undelivered element(s) to allocate revenue to each element in multiple element agreements. When the delivered element does not have stand-alone value or there is insufficient evidence of fair value for the undelivered element(s), we recognize the consideration for the combined unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is generally ratably over the longest period of involvement. Returns or credits related to the sale of products have not had a material impact on our revenues or net loss.

Upfront payments received upon execution of collaborative agreements are recorded as deferred revenue and recognized as collaborative research and development revenue based on a straight-line basis over the period of our continuing involvement with the third party collaborator pursuant to the applicable agreement. Such period generally represents the research and development period set forth in the work plan defined in the respective agreements between us and our third-party collaborators.

Research and development revenue related to services performed under the collaborative arrangements with our corporate collaborators is recognized as the related research and development services are performed and the collectability of the amounts owed is reasonably assured. These research payments received under each respective agreement are not refundable and are generally based on reimbursement of qualified expenses, as defined in the agreements. Research and development expenses under the collaborative research and development agreements generally approximate or exceed the revenue recognized under such agreements over the term of the respective agreements. Deferred revenue may result when we do not expend the required level of effort during a specific period in comparison to funds received under the respective agreement. Pursuant to ASC 808-10, *Collaborative Arrangements*, for joint control and funding development activities, we will not recognize revenue from the reimbursement of the research and development expenses but instead those reimbursements receivable from the joint venture party will be recorded as a reduction in research and development expense.

21

Table of Contents

Milestone payments under collaborative arrangements are recognized as revenue upon achievement of the at risk milestone events, which represent the culmination of the earnings process related to that milestone. Milestone payments are triggered either by the results of our research and development efforts or by events external to us, such as regulatory approval to market a product or the achievement of specified sales levels by a third-party collaborator. As such, the milestones are substantially at risk at the inception of the collaboration agreement, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, we have no future performance obligations related to that milestone payment.

Research and Development Expenses

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 costs are expensed as incurred. Research and development costs paid to third parties under sponsored research agreements are recognized as expense as the related services are performed, generally ratably over the period of service. In addition, reimbursements by Nycomed for research and development expenses incurred by us are recorded as a reduction to research and development expenses. Research and development expenses incurred by Nycomed and reimbursable by us are recorded as an addition to our research and development expenses in the period incurred.

Intangible Assets and Goodwill

We record intangible assets when we acquire other companies and intellectual property rights. The cost of an acquisition is allocated to the assets acquired and liabilities assumed, including intangible assets, with the remaining amount being classified as goodwill. Certain intangible assets such as completed or core technologies are amortized over time.

Goodwill is not amortized to expense but rather periodically assessed for impairment. The allocation of the cost of an acquisition to intangible assets and goodwill therefore has a significant impact on our future operating results. The allocation process requires the extensive use of estimates and assumptions, including estimates of future cash flows expected to be generated by the acquired assets. We are also required to estimate the useful lives of those intangible assets subject to amortization, which determines the amount of amortization that will be recorded in a given future period and how quickly the total balance will be amortized. We periodically review the estimated remaining useful lives of our intangible assets. A reduction in our estimate of remaining useful lives, if any, could result in increased amortization expense in future periods. We assess the impairment of identifiable intangible assets, long-lived assets and goodwill whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important which could trigger an impairment review include the following:

- new information affecting the commercial value of the asset;
- significant underperformance relative to expected historical or projected future operating results;
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business;
- significant negative industry or economic trends;
- significant decline in our stock price for a sustained period; and
- our market capitalization relative to net book value.

When we determine that the carrying value of intangibles, long-lived assets and goodwill may not be recoverable based upon the existence of one or more of the above indicators of impairment, we measure any impairment based on a projected discounted cash flow method using a discount rate determined by our management to be commensurate with the risk inherent in our current business model. The amount of any impairment charge is significantly impacted by and highly dependent upon assumptions as to future cash flows and the appropriate discount rate.

Management believes that the discount rate used in this analysis is reasonable in light of currently available information. The use of different assumptions or discount rates could result in a materially different impairment charge.

We perform a review for impairment of goodwill at least annually in accordance with ASC350, *Intangibles Goodwill and Other*. No impairment of goodwill has been recorded through December 31, 2009. However, there can be no assurance that at the time other periodic reviews are completed, a material impairment charge will not be recorded.

Table of Contents

Accrued Liabilities and Contract Research Liabilities

We incur significant costs associated with third party consultants and organizations for pre-clinical studies, clinical trials, contract manufacturing, validation, testing, and other research and development-related services. We are required to estimate periodically the cost of services rendered but unbilled based on management s estimates of project status. If these good faith estimates are inaccurate, actual expenses incurred could materially differ from our estimates.

Inventories

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.

Stock-Based Compensation

Under the provisions of ASC 718, *Compensation Stock Compensation*, employee stock-based compensation is estimated at the date of grant based on the employee stock award s fair value using the Black Scholes option-pricing model and is recognized as expense ratably over the requisite period in a manner similar to other forms of compensation paid to employees.

We estimate the volatility of our common stock at the date of grant based on the historical volatility of our common stock, consistent with ASC 718, *Compensation Stock Compensation.* We base the risk-free rate that we use in the Black-Scholes option valuation model on the implied yield in effect at the time of option grant on U.S. Treasury zero-coupon issues with equivalent remaining terms. We have never paid any cash dividends on our common stock and we do not anticipate paying any cash dividends in the foreseeable future. Consequently, we use an expected dividend yield of zero in the Black-Scholes option valuation model. ASC 718 requires us to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. For options granted before January 1, 2006, we amortize the fair value on an accelerated basis. For options granted on or after January 1, 2006, we amortize the fair value on a straight-line basis. All options are amortized over the requisite service periods of the awards, which are generally the vesting periods. We may elect to use different assumptions under the Black-Scholes option valuation model in the future, which could materially affect our net income or loss and net income or loss per share.

Results of Operations

Three months ended March 31, 2010 and 2009

Revenues. Net revenues were $7.7 million and $6.2 million for the three months ended March 31, 2010 and 2009, respectively. The increase in total revenues in the three months ended March 31, 2010 was primarily attributable to higher product revenue recognized from sale of certain excipients included in Remoxy to King, as well as higher product revenue from our ALZET and LACTEL business units. In addition, the increase in the first quarter of 2010 reflected higher collaborative research and development revenue from King and Pain Therapeutics, partially offset by lower collaborative research and development revenue recognized from our other agreements.

Collaborative research and development and other revenue

We recognize revenues from collaborative research and development activities and service contracts. We recorded $3.8 million and $3.7 million of collaborative research and development revenue for the three months ended March 31, 2010 and 2009, respectively. Collaborative research and development revenue represents reimbursement of qualified expenses related to collaborative agreements with various third parties to research, develop and commercialize potential products using our drug delivery technologies and revenue recognized from ratable recognition of upfront fees. The slight increase in collaborative research and development revenue in the three months ended March 31, 2010 were primarily attributable to higher revenue recognized in connection with our agreements with King, Pain Therapeutics and feasibility partners, partially offset by lower collaborative research and development revenue recognized in connection with our terminated agreement with Endo and the ratable recognition of the upfront payment under our agreement with Nycomed compared with the same period in 2009.

23

Table of Contents

We received a $10.0 million upfront fee in connection with the license agreement signed with Endo in March 2005 relating to TRANSDUR-Sufentanil. The $10.0 million upfront fee was recognized as revenue ratably over the term of our continuing involvement with Endo with respect to TRANSDUR-Sufentanil. For the three months ended March 31, 2010 and 2009, we recognized zero and $875,000, respectively, in collaborative research and development revenue related to this upfront fee. Our estimate of the remaining term of our continuing involvement was adjusted in the fourth quarter of 2008 as a result of Endo s termination notice received by us in February 2009. The $10.0 million upfront fee from Endo was fully recognized as of December 31, 2009.

We also received a $14.0 million upfront fee in connection with the development and license agreement with Nycomed in November 2006 relating to POSIDUR. The $14.0 million up-front fee is recognized as collaborative research and development revenue ratably over the term of our continuing involvement with Nycomed with respect to POSIDUR. For the three months ended March 31, 2010 and 2009, we recognized $309,000 and $381,000, respectively, in collaborative research and development revenue related to this upfront fee. Our estimate of the remaining term of our continuing involvement was modified in the first quarter and the fourth quarter of 2009 as a result of updated development plans for POSIDUR in Europe.

We also received a $20.0 million upfront fee in connection with the development and license agreement signed with Alpharma (acquired by King) in September 2008 relating to ELADUR. The $20.0 million upfront fee is recognized as collaborative research and development revenue ratably over the term of our continuing involvement with Alpharma (King) with respect to ELADUR. For the three months ended March 31, 2010 and 2009, we recognized $804,000 and $1.0 million, respectively, in collaborative research and development revenue related to this upfront fee. Our estimate of the remaining term of our continuing involvement was modified in the second quarter of 2009 as a result of an updated development plan for ELADUR.

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. The collaborative research and development and other revenues associated with our major collaborators are as follows (in thousands):

	Three months ended March 31,	
	2010	2009
Collaborator		
King Pharmaceuticals, Inc. (King)(1)	$ 2,575	$ 1,924
Pain Therapeutics, Inc. (Pain Therapeutics)	701	276
Nycomed Danmark, APS (Nycomed)(2)	309	381
Endo Pharmaceuticals, Inc. (Endo)(3)		985
Others	231	179
Total collaborative research and development and other revenue	$ 3,816	$ 3,745

Notes:

(1) Amounts related to the ratable recognition of upfront fees were $804,000 and $1.0 million for the three months ended March 31, 2010 and 2009 respectively.

(2) Amounts related to the ratable recognition of upfront fees were $309,000 and $381,000 for the three months ended March 31, 2010 and 2009 respectively. Research and development expenses incurred by us in conjunction with the Nycomed collaboration and reimbursable by Nycomed are recorded as a reduction to total research and development expense.

(3) Amounts related to the ratable recognition of upfront fees were zero and $875,000 for the three months ended March 31, 2010 and 2009 respectively. The Company s agreement with Endo was terminated effective August 26, 2009.

We recognize upfront fees on a straight-line basis over the period in which we have continuing involvement with the third-party collaborator pursuant to the applicable agreement. Such period generally represents the research and development period set forth in the work plan under each collaboration agreement between us and our third-party collaborator.

24

Table of Contents

Product revenue

A portion of our revenues is derived from our product sales, which include our ALZET mini pump product line, our LACTEL biodegradable polymer product line and certain excipients that are included in Remoxy. Net product revenues were $3.9 million and $2.4 million in the three months ended March 31, 2010 and 2009, respectively. The increase in the three months ended March 31, 2010 was primarily attributable to higher product revenue from the sale of certain excipients included in Remoxy to King; revenues in the 2010 period included $551,000 related to a price settlement for shipments to King that occurred in 2008 and the first quarter of 2009 pursuant to the long term supply agreement executed in the third quarter of 2009 as well as $410,000 of product revenue related to the shipment of another excipient that is included in Remoxy in the first quarter of 2010. In addition, we recognized higher product revenue from our ALZET mini pump product line and our LACTEL polymer product line as a result of higher units sold in the three months ended March 31, 2010 compared to the corresponding period in 2009.

Cost of product revenues. Cost of product revenues was $1.4 million and $824,000 for the three months ended March 31, 2010 and 2009, respectively. The increase in the cost of product revenue in the three months ended March 31, 2010 was primarily the result of recognizing $315,000 of cost of goods sold related to the sale of certain excipients to King as well as higher units sold from our ALZET mini pump product line and from our LACTEL polymer product line. Cost of product revenue and gross profit margin will fluctuate from period to period depending upon the product mix in a particular period. Stock based compensation expense recognized related to cost of product revenues was $84,000 and $78,000 for the three months ended March 31, 2010 and 2009, respectively.

As of March 31, 2010 and 2009, we had 22 and 23 manufacturing employees, respectively. 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 $9.4 million and $9.9 million for the three months ended March 31, 2010 and 2009, respectively. Excluding the impact of stock-based compensation expenses, research and development expenses increased by $522,000 in the three months ended March 31, 2010 compared to the corresponding period in 2009. The increase in the three months ended March 31, 2010 were primarily attributable to higher development costs associated with POSIDUR as well as Remoxy, partially offset by lower development costs associated with ELADUR, our biologics programs, our ORADUR-ADHD,TRANSDUR-Sufentanil, and other research programs compared to the corresponding period in 2009 as more fully discussed below. Stock-based compensation expense recognized related to research and development personnel was $1.3 million and $2.3 million for the three months ended March 31, 2010 and 2009, respectively.

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

	Three months ended March 31,	
	2010	**2009**
POSIDUR (1)	$ 4,595	$ 3,488
ELADUR	1,286	1,483
Remoxy and other ORADUR-based opioid products licensed to Pain Therapeutics	850	458
Biologics Programs	247	657
ORADUR-ADHD	238	979
TRANSDUR-Sufentanil	175	418
Others	2,030	2,420
Total research and development expenses (2)	$ 9,421	$ 9,903

(1) In the three months ended March 31, 2010 and 2009, research and development expenses for POSIDUR incurred by us but reimbursable by Nycomed under the terms of our agreement with Nycomed were $523,000 and $1.1 million, respectively, which were accounted for as a reduction of research and development expenses. In the three months ended March 31, 2010 and 2009, research and development expenses for POSIDUR incurred by Nycomed but reimbursable by us under the terms of our agreement with Nycomed were $820,000 and $945,000, respectively, which were accounted for as additional research and development expenses. See Note 2 Strategic Agreements in

the condensed financial statements for more details about our agreement with Nycomed.

(2) Includes stock-based compensation expenses of $1.3 million and $2.3 million for the three months ended March 31, 2010 and 2009, respectively.

Table of Contents

POSIDUR

Our research and development expenses for POSIDUR increased to $4.6 million in the three months ended March 31, 2010 from $3.5 million in the corresponding period in 2009 primarily due to higher costs associated with the Phase III clinical trials for POSIDUR. Research and development expenses for POSIDUR incurred by us but reimbursable by Nycomed under the terms of our agreement with Nycomed were $523,000 and $1.1 million in the three months ended March 31, 2010 and 2009, respectively. Research and development expenses for POSIDUR incurred by Nycomed but reimbursable by us under the terms of our agreement with Nycomed were $820,000 and $945,000 in the three months ended March 31, 2010 and 2009, respectively, which are accounted for as additional research and development expenses. As a result of the collaboration agreement with Nycomed, our research and development expenses increased by $297,000 and decreased by $167,000 in the three months ended March 31, 2010 and 2009, respectively. The net increase or reduction in research and development expenses represents a net reimbursement from or a net payment to Nycomed reflecting that both parties bore 50% of the development expenses incurred through March 31, 2010 defined under the amended collaboration agreement for POSIDUR.

ELADUR

Our research and development expenses for ELADUR decreased to $1.3 million in the three months ended March 31, 2010 from $1.5 million in the corresponding period in 2009. The decrease was primarily due to lower employee costs, animal studies and contract manufacturing expenses related to this product candidate in the three months ended March 31, 2010.

Remoxy and other select ORADUR-based opioid products

Our research and development expenses for Remoxy and other opioids partnered with Pain Therapeutics increased to $850,000 in the three months ended March 31, 2010 from $458,000 in the corresponding period in 2009. The increase in the three months ended March 31, 2010 was primarily due to increased activities to support the resubmission of the Remoxy NDA.

ORADUR-ADHD

Our research and development expenses for ORADUR-ADHD decreased to $238,000 in the three months ended March 31, 2010 from $979,000 in the corresponding period in 2009. The decrease in the three months ended March 31, 2010 was primarily due to decreased formulation and other development activities for this drug candidate.

TRANSDUR-Sufentanil

Our research and development expenses for TRANSDUR-Sufentanil decreased to $175,000 in the three months ended March 31, 2010 from $418,000 in the corresponding period in 2009. The decrease in the three months ended March 31, 2010 was primarily due to decreased external costs after Endo returned the program to us effective August 2009.

Biologics programs

Our research and development expenses for biologics programs decreased to $247,000 in the three months ended March 31, 2010 from $657,000 in the corresponding period in 2009. The decrease in the three months ended March 31, 2010 was primarily due to lower external costs and employee related costs in support of these programs.

Other DURECT research programs

Our research and development expenses for all other programs decreased to $2.0 million in the three months ended March 31, 2010 from $2.4 million in the corresponding period in 2009. The decrease in the three months ended March 31, 2010 were primarily due to lower employee related costs and decreased research and development activities for these programs.

As of March 31, 2010, we had 76 research and development employees compared with 78 as of March 31, 2009. We expect our research and development expenses to increase in the near future.

Table of Contents

We cannot reasonably estimate the timing and costs of our research and development programs due to the risks and uncertainties associated with developing pharmaceutical systems, 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 $3.5 million for the three months ended March 31, 2010, compared to $4.3 million for the corresponding period in 2009. Excluding the impact of stock-based compensation expenses, selling, general and administrative expenses decreased by $253,000 in the three months ended March 31, 2010 compared to the corresponding period in 2009 primarily due to lower patent and marketing related expenses incurred in the three months ended March 31, 2010. Stock-based compensation expense recognized related to selling, general and administrative personnel was $669,000 and $1.2 million for the three months ended March 31, 2010 and 2009, respectively.

As of March 31, 2010, we had 30 selling, general and administrative personnel compared with 29 as of March 31, 2009. We expect selling, general and administrative expenses to remain comparable in the near future.

Other income (expense). Interest and other income was $11,000 for the three months ended March 31, 2010, compared to $179,000 for the corresponding period in 2009. The decrease in interest income was primarily the result of lower yields as well as lower average cash and investment balances during the three months ended March 31, 2010 compared to the corresponding period in 2009.

Interest and other expense was $2,000 for the three months ended March 31, 2010, compared to $11,000 for the corresponding period in 2009. The decrease in interest expense in the three months ended March 31, 2010 compared with the same period of 2009 was primarily due to a reduction in debt.

Liquidity and Capital Resources

We had cash, cash equivalents and investments totaling $35.8 million at March 31, 2010 compared to $41.6 million at December 31, 2009. These balances include $432,000 and $431,000 of interest-bearing marketable securities classified as restricted investments on our balance sheets as of March 31, 2010 and December 31, 2009, respectively. The decrease in cash, cash equivalents and investments during the three months ended March 31, 2010 was primarily the result of ongoing operating expenses, partially offset by payments received from customers.

Working capital was $31.0 million and $34.8 million at March 31, 2010 and December 31, 2009, respectively. The decrease in working capital was primarily attributable to an increase in our operating expenditures in the three months ended March 31, 2010.

We used $5.7 million of cash in operating activities for the three months ended March 31, 2010 compared to $5.6 million for the corresponding period in 2009. The cash used for operations was primarily to fund operations as well as our working capital requirements. The increase in cash used for operations was primarily attributable to the decreases in accounts receivable from our third party collaborators and prepaid expenses for the three months ended March 31, 2010, partially offset by increases in accrued liabilities and contract research liability compared to the corresponding period in 2009.

We received $981,000 of cash for investing activities for the three months ended March 31, 2010 compared to $387,000 of cash used for the corresponding period in 2009. The increase in cash received in investing activities was primarily due to an increase in net proceeds from maturities of available-for-sale securities for the three months ended March 31, 2010 compared to the corresponding period in 2009.

Table of Contents

We used $1,000 of cash from financing activities for the three months ended March 31, 2010 compared to $29,000 of cash received for the corresponding period in 2009. The decrease in cash provided by financing activities was primarily due to lower proceeds from exercises of stock options in the three months ended March 31, 2010 compared to the corresponding period in 2009.

We anticipate that cash used in operating and investing activities will increase in the near future as we continue to research, develop and manufacture our products through internal efforts and partnering activities.

During the three months ended March 31, 2010, we believe there have been no significant changes in our future payments due under contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009.

We anticipate incurring capital expenditures of approximately $500,000 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.

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 systems 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.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Sensitivity

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. Fixed rate securities may have their fair market value adversely impacted due to fluctuations in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates.

Our primary investment objective is to preserve principal while at the same time maximizing yields without significantly increasing risk. Our portfolio includes money markets funds, commercial paper, medium-term notes, corporate notes, government securities and corporate bonds. The diversity of our portfolio helps us to achieve our investment objectives. As of March 31, 2010, all of our investments have a remaining maturity of one year or less. As of March 31, 2010, approximately 81% of our investment portfolio is composed of investments with original maturities of one year or less and approximately 8% of our investment portfolio matures less than 90 days from the date of purchase.

The following table presents the amounts of our cash equivalents and investments that may be subject to interest rate risk and the average interest rates as of March 31, 2010 (dollars in thousands). The amounts presented in the table below approximate fair value.

	Total
Cash equivalents:	
Fixed rate	$ 1,899
Average fixed rate	0.17%
Variable rate	$ 880
Average variable rate	0.06%
Short-term investments:	
Fixed rate	$ 31,827
Average fixed rate	0.44%
Restricted investments:	
Fixed rate	$ 432
Average fixed rate	0.28%
Total investment securities	$ 35,038
Average rate	0.39%

Item 4. Controls and Procedures

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

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

Table of Contents

PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any material legal proceedings.

Item 1A. Risk Factors

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

Risks Related To Our Business

Development of our pharmaceutical systems is not complete, and we cannot be certain that our pharmaceutical systems 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 systems under development. For each pharmaceutical system 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 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 system;
- 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 system 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 selected the drug dosages nor finalized the formulation or the system design of POSIDUR, TRANSDUR-Sufentanil, ELADUR, our ORADUR-based drug candidates other than Remoxy, and we have limited experience in developing such products. We may not be able to finalize the design or formulation of any of these pharmaceutical systems. In addition, we may select components, solvents, excipients or other ingredients to include in our pharmaceutical systems 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 pharmaceutical systems. Even after we complete the design of a pharmaceutical system, the pharmaceutical system must still complete required clinical trials and additional safety testing in animals before approval for commercialization. We are continuing testing and development of our pharmaceutical systems and may explore possible design or formulation changes to address issues of safety, manufacturing efficiency and performance. We and our collaborators may not be able to

complete development of any pharmaceutical systems 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, Remoxy and our ORADUR-based drug candidates other than Remoxy, or other pharmaceutical systems, we will not be able to earn revenue from them, which would materially harm our business.

Table of Contents

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

Before we or our third-party collaborators can obtain government approval to sell any of our pharmaceutical systems, 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 An NDA has been submitted, in response to which the FDA has provided a Complete Response Letter. King, which holds the commercialization rights to Remoxy, has stated that it has undertaken a likeability study and a pharmacokinetic trial in volunteers and plans to resubmit the NDA in the fourth quarter of 2010. There can be no assurance that any resubmission of the NDA by King will be timely or sufficient to gain approval of Remoxy.

POSIDUR To date, we have completed several Phase II studies in various surgeries and held an end-of-Phase II meeting with the FDA. We are currently conducting BESST (Bupivacaine Effectiveness and Safety in SABER Trial), which is intended to be the pivotal Phase III clinical trial in the U.S. BESST is an international, multi-center, randomized, double-blind, controlled trial evaluating the safety, efficacy, and pharmacokinetics of POSIDUR in approximately 300 patients undergoing a variety of general abdominal surgical procedures. Nycomed is conducting Phase IIb studies in hysterectomy patients and shoulder surgery patients. These trials are being conducted by Nycomed in a different manner than U.S. studies and are designed to be suitable for European regulatory approval purposes. There can be no assurance that these trials will be successful. Furthermore, there can be no assurance that our planned development program for POSIDUR will generate data and information that will be deemed sufficient for marketing approval by the FDA or other regulatory agencies.

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. During 2009, we transitioned the program back to our control from Endo Pharmaceuticals. 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 was completed and positive results were reported in the fourth quarter of 2007. King, to whom we have granted worldwide development and commercialization rights for ELADUR, has begun a Phase IIb clinical trial to evaluate ELADUR for the treatment of chronic low back pain. There can be no assurance that King will be able to successfully develop ELADUR to obtain marketing approval by the FDA or other regulatory agencies.

We are currently in the clinical, preclinical or research stages with respect to all our other pharmaceutical systems 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 pharmaceutical systems. These studies include laboratory performance studies and safety testing, clinical trials and 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.

While some of our clinical trials described above 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. 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. Side effects, toxicity or other safety issues associated with the use of our drug candidates that could require us to perform additional studies or halt development of our drug candidates. We and our collaborators may not be permitted to begin or continue our planned clinical trials for our potential pharmaceutical systems. If our trials are permitted, our potential pharmaceutical systems may not prove to be safe or produce their intended effects. In addition, 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 systems which we have not planned or anticipated. For example, according to Pain Therapeutics, the FDA has indicated that additional non-clinical data will be required prior to regulatory approval for Remoxy. This additional data could delay commercialization of Remoxy and harm our business and financial condition.

31

Table of Contents

The length of clinical trials will depend upon, among other factors, the rate of trial site and patient enrollment and the number of patients required to be enrolled in such studies. We or our third-party collaborators may fail to obtain adequate levels of patient enrollment in our clinical trials. Delays in planned patient enrollment may result in increased costs, delays or termination of clinical trials, which could have a material adverse effect on us. In addition, even if we or our third-party collaborators enroll the number of patients we expect in the time frame we expect, such clinical trials may not provide the data necessary to support regulatory approval for the pharmaceutical systems for which they were conducted. Additionally, we or our third-party collaborators may fail to effectively oversee and monitor these clinical trials, which would result in increased costs or delays of our clinical trials. Even if these clinical trials are completed, we or our third-party collaborators may fail to complete and submit a new drug application as scheduled.

The FDA may not clear any such application in a timely manner or may deny the application entirely. Data already obtained from preclinical studies and clinical trials of our pharmaceutical systems do not necessarily predict the results that will be obtained from later preclinical studies and clinical trials. Moreover, preclinical and clinical data such as ours are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a pharmaceutical system under development could delay or prevent regulatory clearance of the potential pharmaceutical system, resulting in delays to the commercialization of our pharmaceutical system, 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 pharmaceutical systems, and thus our pharmaceutical systems may not be approved for marketing.

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

The manufacture and marketing of our pharmaceutical systems 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 data which may cause lengthy delays and increased costs to our programs.

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 systems. 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 pharmaceutical systems.

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 systems 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 systems, which will limit our ability to generate revenue.

32

Table of Contents

Many of our drug candidates under development including Remoxy and TRANSDUR-Sufentanil are subject to mandatory Risk Evaluation and Mitigation Strategy (REMS) programs, a new requirement by the FDA, 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. The FDA has authority to require a REMS under the Food and Drug Administration Amendments Act of 2007 (FDAAA) when necessary to ensure that the benefits of a drug outweigh the risks.

According to the FDA, opioid drugs have benefit when used properly and are a necessary component of pain management for certain patients. Opioid drugs have serious risks when used improperly. The FDA, drug manufacturers, and others have taken a number of steps in the past to prevent misuse, abuse and accidental overdose of these drugs, including providing additional warnings in product labeling, implementing risk management plans, conducting inter-agency collaborations, and issuing direct communications to both prescribers and patients. Despite these efforts, the rates of misuse and abuse, and of accidental overdose of opioids, have risen over the past decade. The FDA believes that establishing a REMS for opioids will reduce these risks, while still ensuring that patients with legitimate need for these drugs will continue to have appropriate access.

According to the FDA, it recognizes the need to achieve balance between appropriate access and risk mitigation, and believes an effective strategy would benefit from input from industry, patient advocacy groups, the pain and addiction treatment communities, the general public, and other stakeholders. In the first of a series of meetings with stakeholders, the FDA invited those companies that market the affected opioid drugs to a meeting with the agency on March 3, 2009 to discuss REMS development. Additional steps will include discussions with other federal agencies and non-government institutions, including patient and consumer advocates, representatives of the pain and addiction treatment communities, other health care professionals, and other interested parties. The FDA also held public meetings on May 27 and 28, 2009 to allow for broader public input and participation. On December 4, 2009, FDA held a public meeting with the drug company sponsors to hear from them about the status of the development of a proposed REMS and their views regarding the specific features of the REMS. Through this process, the FDA hopes to gain valuable information that will lead to practical and effective solutions for development of a REMS and for appropriate use of these opioid drug products.

Many of our drug candidates including Remoxy, our other ORADUR-opioid drug candidates and TRANSDUR-Sufentanil are subject to the REMS requirement. 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.

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 systems 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 systems. We have entered into agreements with Pain Therapeutics, Nycomed, Alpharma (acquired by King), Orient Pharma 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, POSIDUR, ELADUR and other product candidates, respectively, 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 pharmaceutical systems, 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. They may also conduct their activities in a manner that is different from the manner we would have chosen, had we been developing such pharmaceutical systems ourselves. Further, our collaborators may elect not to develop or commercialize pharmaceutical systems arising out of our collaborative arrangements or not devote sufficient resources to the development, clinical trials, regulatory approval, manufacture, marketing or sale of these pharmaceutical systems. If any of these events occur, we may not recognize revenue from the commercialization of our pharmaceutical systems 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 pharmaceutical systems. We may not be able to control public disclosures made by some of our third-party collaborators, which could negatively impact our stock price.

33

Table of Contents

Our near-term 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

Our near-term 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 pharmaceutical systems, or can lead to lengthy, expensive litigation or arbitration. In general, our collaboration agreements, including our agreements with Pain Therapeutics with respect to Remoxy and other ORADUR-based products incorporating specified opioids, Nycomed with respect to POSIDUR, Alpharma (acquired by King) with respect to ELADUR and Orient Pharma with respect to ORADUR-ADHD, 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.

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

Our near-term 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 clinical trial developments, regulatory approvals or sales accomplishments. To the extent third-party collaborators do not achieve such 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 systems. The negotiation and consummation of these type 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 systems. 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 pharmaceutical systems. 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.

Table of Contents

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:

- 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;
- 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 systems;
- costs involved in establishing manufacturing capabilities for clinical and commercial quantities of our pharmaceutical systems;
- competing technological and market developments;
- market acceptance of our pharmaceutical systems;
- 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 systems 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 loss of sales, increased costs, and reduced revenues.

We and our third-party collaborators may not be able to manufacture sufficient quantities of our pharmaceutical systems 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 systems 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 pharmaceutical systems are complex. Except with respect to Remoxy, we and our third-party collaborators, where relevant, have not yet completed development of the manufacturing process for any pharmaceutical systems or components, including POSIDUR, TRANSDUR-Sufentanil, ELADUR, and other ORADUR-based drug candidates. If we and our third-party collaborators, where relevant, fail to timely complete the development of the manufacturing process for our pharmaceutical systems, we and our third-party collaborators, where relevant, will not be able to timely produce product for clinical trials and commercialization of our pharmaceutical systems. We have also committed to manufacture and supply pharmaceutical systems 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 pharmaceutical system or component at an acceptable cost, then we and our third-party collaborators may not be able to commercialize that pharmaceutical system 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 systems under good manufacturing practices (GMP), including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and other ORADUR-based drug candidates. We have not manufactured commercial quantities of any of our pharmaceutical systems. In the future, we intend to develop additional manufacturing capabilities for our pharmaceutical systems and components to meet our demands and those of our third-party collaborators by contracting with third-party manufacturers and by construction of additional manufacturing space at our current facilities in Cupertino, CA, Vacaville, CA and Pelham, AL. We have limited experience building and validating manufacturing facilities, and we may not be able to accomplish these tasks in a timely manner.

Table of Contents

If we and our third-party collaborators, where relevant, are unable to manufacture pharmaceutical systems 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 pharmaceutical systems 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 pharmaceutical systems and those of our third-party collaborators.

We have entered into a supply agreement with Corium International, Inc. for clinical and commercial supplies of ELADUR and a supply agreement with Hospira Worldwide, Inc. for clinical and commercial supplies of POSIDUR. 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 systems or supply required components for our pharmaceutical systems. 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.

If we or our third-party collaborators cannot manufacture pharmaceutical systems 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 systems 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 pharmaceutical systems, 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 systems under development; or
- FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects in our pharmaceutical systems.

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 pharmaceutical systems. If we, our third-party collaborators or our respective suppliers do not achieve compliance for our pharmaceutical systems 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 pharmaceutical systems.

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, 2010, had an accumulated deficit of approximately $320.5 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 pharmaceutical systems, obtain the required regulatory clearances, and manufacture and market our proposed pharmaceutical systems. Development of

pharmaceutical systems 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 pharmaceutical systems. The license fees for these technologies or rights would increase the costs of our pharmaceutical systems.

Table of Contents

To date, we have not generated significant revenue from the commercial sale of our pharmaceutical systems and do not expect to do so in the near future. Our current product revenues are from the sale of the ALZET product line and the sale of LACTEL biodegradable polymers, and from payments under collaborative research and development agreements with third parties. 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 pharmaceutical systems 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 POSIDUR 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 POSIDUR in the United States if POSIDUR is approved for marketing by the FDA. Developing a sales force will require substantial expenditures. We have limited sales and marketing experience, and may not be able to effectively recruit, train or retain sales personnel. We may not be able to effectively sell our pharmaceutical systems, 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 pharmaceutical systems 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 pharmaceutical systems;
- 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 pharmaceutical systems; or
- build up inventory in excess of demand thereby limiting future purchases of our pharmaceutical systems 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 pharmaceutical systems will hurt our business and financial results.

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

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 pharmaceutical systems. For example, we currently depend on third-party vendors to manage and monitor our clinical trials and to perform critical manufacturing steps for our pharmaceutical systems. These third parties may not execute their responsibilities and tasks competently or in a timely fashion. We rely on third-parties to manufacture or perform manufacturing steps relating to our pharmaceutical systems 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 pharmaceutical systems. 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.

Table of Contents

Key components of our pharmaceutical systems 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 pharmaceutical systems (including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and our other ORADUR-based drug candidates) 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-opioids 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 system 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 pharmaceuticals systems, but do not have in place long term supply agreements with respect to all of the components of any of our pharmaceutical system 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 pharmaceutical systems 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 pharmaceutical systems, causing us to lose sales, incur additional costs, delay new product introductions and could harm our reputation.

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 success will depend in part on our ability to obtain and maintain patents, maintain trade secret protection and operate without infringing the proprietary rights of others. As of April 30, 2010, we held 58 issued U.S. patents and 380 issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have 84 pending U.S. patent applications and have filed 107 patent applications under the Patent Cooperation Treaty, from which 536 national phase applications are currently pending in Europe, Australia, Japan, Canada and other countries. Our patents expire at various dates starting in 2012.

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 or circumvented. 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. The recent decisions of the U.S. Supreme Court (e.g., *KSR v. Telefex, EBay v. MercExchange*) and other courts (e.g., *In re Seagate*) 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, bills are pending before the U.S. Congress that may fundamentally change the patent laws of the U.S. on issues ranging from priority entitlement, filing and prosecution matters to enforcement and damages. These changes and proposed reforms 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.

38

Table of Contents

We are party to several collaborative agreements. 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 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, Inc. v. Genentech, Inc.* 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 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 proceedings declared by the USPTO may be necessary to determine the priority of inventions with respect to our 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.

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

We and our collaborators may be exposed to future litigation by third parties based on claims that our pharmaceutical systems 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 systems 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 pharmaceutical systems, which would be costly and time-consuming.

We may be required to obtain rights to certain drugs

Some of the pharmaceutical systems that we may choose to develop may include proprietary drugs to which we do not have commercial rights. To complete the development and commercialization of pharmaceutical systems containing drugs to which we do not have commercial rights, we will be required to obtain rights to those drugs. We may not be able to do this at an acceptable cost, if at all. If we are not able to obtain

required rights to commercialize certain drugs, we may not be able to complete the development of pharmaceutical systems which require use of those drugs. This could result in the cessation of certain development projects and the potential write-off of certain assets.

Table of Contents

Technologies and businesses which we have acquired may be difficult to integrate, disrupt our business, dilute stockholder value or divert management attention. We may also acquire additional businesses or technologies in the future, which could have these same effects

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 systems 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 pharmaceutical systems 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 pharmaceutical systems 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 pharmaceutical systems containing controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state, federal 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 pharmaceutical systems containing controlled substances and subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of our pharmaceutical systems 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, which impacted our financial statements. We are required to perform periodic impairment reviews of our goodwill at least annually. 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 2009 and determined that goodwill was not impaired as of December 31, 2009. 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.

Table of Contents

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 December 31, 2009, no assurance can be given that further 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.

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 systems, 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.

41

Table of Contents

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 systems 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 pharmaceutical systems 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, Remoxy and other ORADUR-based drug candidates, if approved, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, 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, King, Knoll, Janssen, Medtronic, Endo, AstraZeneca, Arrow International, Tricumed, I-Flow (Kimberly-Clark), Cumberland Pharmaceuticals, Covidien, Shire, Johnson & Johnson, Eli Lilly and Novartis. 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, Javelin Pharmaceuticals, Cumberland Pharmaceuticals, Egalet, Acura 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.

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 pharmaceutical systems. Our competitors may develop products that are safer, more effective or less costly than our pharmaceutical systems 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 pharmaceutical systems even if commercialized. Chronic and post-operative pain are currently being treated by oral medication, transdermal drug delivery systems, such as drug patches, and implantable drug delivery devices which will be competitive with our pharmaceutical systems. 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 pharmaceutical systems 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 pharmaceutical systems 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 pharmaceutical systems, 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 pharmaceutical systems, 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 pharmaceutical systems. A product liability claim could also significantly harm our reputation and delay market acceptance of our pharmaceutical systems.

42

Table of Contents

Acceptance of our pharmaceutical systems 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 future products, including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and other ORADUR-based drug candidates. Even if approved for marketing, our pharmaceutical systems 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 pharmaceutical systems will depend in part on the extent to which appropriate reimbursement levels for the cost of our pharmaceutical systems 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 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.

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

Broad use of our pharmaceutical systems will require extensive training of numerous physicians on the proper and safe use of our pharmaceutical systems. 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 pharmaceutical systems may be unable to rapidly train physicians in numbers sufficient to generate adequate demand for our pharmaceutical systems. Any delay in training would materially delay the demand for our pharmaceutical systems 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.

43

Table of Contents

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 increasing 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 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 pharmaceutical systems, 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 pharmaceutical systems 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 (such as Pain Therapeutics or its commercialization sub-licensee King, Nycomed, Alpharma (now owned by King) and Orient Pharma) to successfully develop and commercialize the respective pharmaceutical systems 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 or other pharmaceutical systems;

- announcements of FDA non-approval of our pharmaceutical systems, 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 pharmaceutical systems, clinical trials, manufacturing processes or sales and marketing activities, or those of our third party collaborators;

announcements of technological innovations, patents or new products by our competitors;

regulatory developments in the United States and foreign countries;

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

Table of Contents

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;

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, would 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, Delaware law and our stockholder rights plan contain provisions that could discourage another company from acquiring us.

Provisions of Delaware law, our certificate of incorporation, bylaws and stockholder rights plan 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 dividend on our common stock, commonly referred to as a poison pill, which can be triggered after a person or group acquires 17.5% or more of common stock;

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;

Table of Contents

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None

Item 3. Defaults Upon Senior Securities

None

Item 4. [Removed And Reserved]

Item 5. Other Information

None

Item 6. Exhibits

10.57	Amendment No. 1 to Development and License Agreement between DURECT Corporation and Nycomed Danmark, APS dated February 18, 2010. *
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.
32.2	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of Matthew J. Hogan.

* Confidential treatment requested with respect to certain portions of this Exhibit.

Table of Contents

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 10, 2010

By: /s/ MATTHEW J. HOGAN
Matthew J. Hogan
Chief Financial Officer and Principal Accounting Officer

Date: May 10, 2010

Table of Contents

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