DURECT CORP
Form 10-Q
August 04, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2009

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 Smaller reporting company ¨ Non-accelerated filer ¨
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 July 31, 2009, there were 82,199,859 shares of the registrant s Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

	June 30, 2009 (unaudited)	December 31, 2008 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,024	$ 29,445
Short-term investments	24,507	20,836
Short-term restricted investments	372	624
Accounts receivable (net of allowances of $90 and $113, respectively)	2,336	4,055
Inventories	2,737	3,474
Prepaid expenses and other current assets	3,037	1,850
Total current assets	43,013	60,284
Property and equipment, net	4,955	5,971
Goodwill	6,399	6,399
Intangible assets, net	133	157
Long-term investments	6,528	1,362
Long-term restricted investments	428	425
Other long-term assets	368	276
Total assets	$ 61,824	$ 74,874
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 846	$ 1,018
Accrued liabilities	4,135	5,204
Contract research liability	616	995
Deferred revenue, current portion	8,074	9,235
Other short-term liabilities	421	431
Total current liabilities	14,092	16,883
Deferred revenue, non-current portion	19,552	19,771
Other long-term liabilities	614	656
Commitments Stockholders equity:		
Common stock	8	8
Additional paid-in capital	327,261	321,067
Accumulated other comprehensive income	53	81
Accumulated deficit	(299,756)	(283,592)
Stockholders equity	27,566	37,564
Total liabilities and stockholders equity	$ 61,824	$ 74,874

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

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DURECT CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Collaborative research and development and other revenue	$ 2,606	$ 3,867	$ 6,351	$ 8,136
Product revenue, net	2,271	2,436	4,686	4,605
Total revenues	4,877	6,303	11,037	12,741
Operating expenses:				
Cost of revenues (1)	837	982	1,661	1,804
Research and development (1)	7,866	9,898	17,769	19,532
Selling, general and administrative (1)	3,777	4,086	8,034	7,976
Total operating expenses	12,480	14,966	27,464	29,312
Loss from operations	(7,603)	(8,663)	(16,427)	(16,571)
Other income (expense):				
Interest and other income	106	368	285	936
Interest and other expense	(11)	(304)	(22)	(759)
Net other income	95	64	263	177
Net loss	$ (7,508)	$ (8,599)	$ (16,164)	$ (16,394)
Net loss per share, basic and diluted	$ (0.09)	$ (0.11)	$ (0.20)	$ (0.22)
Shares used in computing basic and diluted net loss per share	82,138	75,430	82,081	74,772

(1) Stock-based compensation related to the following:

Cost of revenues	$ 117	$ 31	$ 195	$ 66
Research and development	1,327	1,360	3,608	2,967
Selling, general and administrative	864	674	2,035	1,449
Total stock-based compensation	$ 2,308	$ 2,065	$ 5,838	$ 4,482

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

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DURECT CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six months ended June 30,	
	2009	**2008**
Cash flows from operating activities		
Net loss	$ (16,164)	$ (16,394)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,508	1,342
Stock-based compensation	5,838	4,482
Inventory write-off	126	
Changes in assets and liabilities:		
Accounts receivable	1,719	542
Inventories	641	(675)
Prepaid expenses and other assets	(1,279)	185
Accounts payable	(172)	(1,085)
Accrued and other liabilities	(1,482)	1,235
Contract research liability	(379)	(1,268)
Interest payable on convertible notes		(62)
Deferred revenue	(1,380)	(2,579)
Total adjustments	5,140	2,117
Net cash used in operating activities	(11,024)	(14,277)
Cash flows from investing activities		
Purchases of property and equipment	(85)	(649)
Purchase of intangible assets		(25)
Purchases of available-for-sale securities	(27,963)	(10,234)
Proceeds from maturities of available-for-sale securities	18,193	18,498
Proceeds from sales of available-for-sale securities	1,154	
Net cash (used in) provided by investing activities	(8,701)	7,590
Cash flows from financing activities		
Payments on equipment financing obligations	(21)	(19)
Net proceeds from issuances of common stock	325	562
Net cash provided by financing activities	304	543
Net decrease in cash and cash equivalents	(19,421)	(6,144)
Cash and cash equivalents, beginning of the period	29,445	37,589
Cash and cash equivalents, end of the period	$ 10,024	$ 31,445

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

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DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Nature of Operations

DURECT Corporation (the Company) was incorporated in the state of Delaware on February 6, 1998. The Company is a pharmaceutical company developing therapies based on its proprietary drug formulations and delivery platform technologies. The Company has several products under development by itself and with third party collaborators. The Company also manufactures and sells osmotic pumps used in laboratory research, and designs, develops and manufactures a wide range of standard and custom biodegradable polymers 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 June 30, 2009, the operating results for the three and six months ended June 30, 2009 and 2008, and cash flows for the six months ended June 30, 2009 and 2008. The Company has evaluated subsequent events through the time of filing this Form 10-Q on August 4, 2009, which is the date that these financial statements have been filed with the Securities and Exchange Commission (SEC). All appropriate subsequent event disclosures have been made in the notes to our unaudited condensed financial statements. The balance sheet as of December 31, 2008 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 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):

	June 30, 2009 (unaudited)	December 31, 2008
Raw materials	$ 565	$ 765
Work in process	825	1,188
Finished goods	1,347	1,521
Total inventories	$ 2,737	$ 3,474

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 exists, the price is fixed or determinable and the collectability of the amounts owed is reasonably assured. The Company recognizes revenue from the sale of its products and license and collaboration agreements pursuant to Staff

Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force (EITF) Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. Multiple element agreements entered into are evaluated under the provision of EITF 00-21. 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.

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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. Pursuant to EITF Issue 07-1 (EITF 07-1), *Accounting for Collaborative Arrangements,* for joint control and funding development activities, the Company 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.

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 we have no future performance obligations related to that milestone payment.

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 June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Collaborator				
King Pharmaceuticals, Inc. (King)(1)	$ 1,632	$	$ 3,556	$
Endo Pharmaceuticals, Inc. (Endo)(2)		836	985	1,634
Nycomed Danmark, APS (Nycomed)(3)	381	763	763	1,525
Pain Therapeutics, Inc. (Pain Therapeutics)	46	1,861	322	4,009
Others	547	407	725	968
Total collaborative research and development and other revenue	$ 2,606	$ 3,867	$ 6,351	$ 8,136

Notes:

(1) Amounts related to amortization of upfront fees were $804,000 and $1.8 million for the three and six months ended June 30, 2009, respectively, compared to zero for each of the corresponding periods in 2008.

(2) Amounts related to amortization of upfront fees were zero and $875,000 for the three and six months ended June 30, 2009, respectively, compared to $547,000 and $1.1 million for the corresponding periods in 2008. The Company s agreement with Endo will terminate effective August 26, 2009.

(3) Amounts related to amortization of upfront fees were $381,000 and $763,000 for the three and six months ended June 30, 2009, respectively, compared to $763,000 and $1.5 million for the corresponding periods in 2008. 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.

The Company amortizes 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.

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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 June 30,		Six months ended June 30,	
	2009	2008	2009	2008
POSIDUR (1)	$ 2,918	$ 2,491	$ 6,406	$ 4,346
ELADUR	694	2,324	2,177	4,386
Remoxy and other select ORADUR-based opioid drug candidates	476	1,618	934	3,489
Biologics Programs	415	1,396	1,072	2,308
TRANSDUR-Sufentanil	353	314	771	636
Others	3,010	1,755	6,409	4,367
Total research and development expenses (2)	$ 7,866	$ 9,898	$ 17,769	$ 19,532

(1) In the three and six months ended June 30, 2009, research and development expenses for POSIDUR incurred by us but reimbursable by Nycomed under the terms of the Company s agreement with Nycomed were $855,000 and $2.0 million, respectively, compared to $904,000 and $1.7 million for the corresponding periods in 2008, which were accounted for as a reduction of research and development expenses. In the three and six months ended June 30, 2009, research and development expenses for POSIDUR incurred by Nycomed but reimbursable by us under the terms of the Company s agreement with Nycomed were $1.1 million and $2.1 million, respectively, compared to $784,000 and $1.1 million for the corresponding periods in 2008, which were accounted for as additional research and development expenses. Please see Note 2 Strategic Agreements for more details about the Company s agreement with Nycomed.

(2) Includes stock-based compensation expenses of $1.3 million and $3.6 million for the three and six months ended June 30, 2009, compared to $1.4 million and $3.0 million for the corresponding periods in 2008.

Comprehensive Loss

Components of other comprehensive income (loss) 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 June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Net loss	$ (7,508)	$ (8,599)	$ (16,164)	$ (16,394)
Net change in unrealized gain on available-for-sale investments, net of tax	47	(84)	(28)	(27)
Comprehensive loss	$ (7,461)	$ (8,683)	$ (16,192)	$ (16,421)

Accumulated other comprehensive income as of June 30, 2009 and December 31, 2008 is entirely comprised of net unrealized gains, net of taxes.

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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, convertible subordinated notes) outstanding during the year, if dilutive, using the treasury stock method for options and warrants and the if-converted method for convertible subordinated notes.

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Outstanding common stock equivalents not included in diluted net loss per share because their effect would be anti-dilutive				
Options to purchase common stock	16,361	15,693	16,323	15,932
Convertible notes		6,281		6,887
Warrants	1	1	1	1
Total	16,362	21,975	16,324	22,820

Shipping and Handling

Costs related to shipping and handling are included in cost of revenues for all periods presented.

Operating Leases

The Company leases administrative, manufacturing and laboratory facilities under operating leases. Lease agreements may include rent holidays, rent escalation clauses and tenant improvement allowances. The Company recognizes scheduled rent increases on a straight-line basis over the lease term beginning with the date the Company takes possession of the leased space. The Company records tenant improvement allowances as deferred rent liabilities on the balance sheets and amortizes the deferred rent over the terms of the lease to rent expense on the statements of operations.

Recent Accounting Pronouncements

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*. This standard replaces SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, and establishes only two levels of U.S. generally accepted accounting principles (GAAP), authoritative and nonauthoritative. The FASB Accounting Standards Codification (the Codification) will become the single source for all authoritative GAAP recognized by the FASB. All other non-grandfathered, non-SEC accounting literature not included in the Codification will become nonauthoritative. This standard is effective for financial statements for interim or annual reporting periods ending after September 15, 2009. The Company will begin to use the new guidelines and numbering system prescribed by the Codification when referring to GAAP in the third quarter of fiscal 2009. As the Codification was not intended to change or alter existing GAAP, it will not have any impact on the Company s financial statements.

In May 2009, the FASB issued SFAS No. 165, Subsequent Events (SFAS No. 165). This standard modifies the names of the two types of subsequent events either as recognized subsequent events (previously referred to in practice as Type I subsequent events) or non-recognized subsequent events (previously referred to in practice as Type II subsequent events). In addition, the standard modifies the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued (for public entities) or available to be issued (for nonpublic entities). It also requires the disclosure of the date through which subsequent events have been evaluated. The Company began applying the provisions of SFAS No.165 in the second quarter of 2009 and its adoption did not impact the Company s financial statements, other than the disclosures required by SFAS No. 165. See Note 1 for additional disclosures pursuant to SFAS No. 165.

In April 2009, the FASB issued three Staff Positions (FSP) that were intended to provide additional application guidance and enhanced disclosures regarding fair value measurements and impairments of securities. FSP No. 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*, provides additional guidelines for estimating fair value in accordance with SFAS No. 157, *Fair Value Measurements.* FSP No. 115-2, *Recognition and Presentation*

of Other-Than-Temporary Impairments, changes existing accounting requirements for other-than-temporary-impairment (OTTI) for debt securities by replacing the current requirement that a holder have the positive intent and ability to hold an impaired security to recovery in order to conclude an impairment was temporary with a requirement that an entity conclude it does not intend to sell an impaired security and it will not be required to sell the security before the recovery of its amortized cost basis. FSP No. 107-1 and Accounting Principles Board (APB) Opinion No. 28-1, *Interim Disclosures about Fair*

Value of Financial Instruments, increases the frequency of fair value disclosures. These FSPs are effective for fiscal years and interim periods ended after June 15, 2009. The Company adopted these FSPs in the second quarter of 2009 and its adoption did not have any impact on the Company s financial statements.

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In May 2008, the FASB issued Staff Position No APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement) (FSP APB 14-1). FSP APB 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash or other assets on conversion, either in part or in full, to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that results in the recognition of interest expense equal to the issuer s nonconvertible debt borrowing rate. This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. This FSP must be applied retrospectively to all periods presented. The adoption of FSP APB 14-1 did not have an impact on the Company s financial statements.

In February 2008, the FASB issued FASB Staff Position No. FSP 157-2, Effective Date of FASB Statement No. 157 , which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except for those items that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, on January 1, 2008, the Company adopted provisions of SFAS 157 with respect to its financial assets and liabilities. On January 1, 2009, the Company adopted the provisions of FSP 157-2 for its non-financial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis. These include goodwill and other non-amortizable intangible assets. The adoption of FSP 157-2 did not have an impact on the Company s financial statements.

In December 2007, the Emerging Issues Task Force of the FASB issued a consensus on Issue No. 07-1 (EITF 07-1), *Accounting for Collaborative Arrangements.* The scope of EITF 07-1 is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The Task Force concluded that revenue transactions with third parties and associated costs incurred should be reported in the appropriate line item in each company s financial statements pursuant to the guidance in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The Task Force also concluded that the equity method of accounting under Accounting Principles Board Opinion 18, *The Equity Method of Accounting for Investments in Common Stock*, should not be applied to arrangements that are not conducted through a separate legal entity. The Task Force also concluded that the income statement classification of payments made between the parties in an arrangement should be based on a consideration of the following factors: the nature and terms of the arrangement; the nature of the entities operations; and whether the parties payments are within the scope of existing GAAP. To the extent such costs are not within the scope of other authoritative accounting literature, the income statement characterization for the payments should be based on an analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The provisions of EITF 07-1 are effective for fiscal years beginning on or after December 15, 2008, and companies are required to apply the provisions through retrospective application to all collaborative arrangements existing at adoption as a change in accounting principle. The adoption of EITF 07-1 did not have an impact on the Company s financial statements.

Note 2. Strategic Agreements

Agreement with Alpharma (acquired by King)

In September 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. The agreement became effective in October 2008 after clearance under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976. 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 million, with possible additional payments of up to $93 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 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 Company will perform development activities through completion of Phase 2, and formulation and manufacturing scale-up activities for the program, the costs of which shall be reimbursed by Alpharma. 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.

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For the three and six months ended June 30, 2009, the Company recognized $804,000 and $1.8 million as collaborative research and development revenue from the amortization of the $20.0 million upfront fee received, and $458,000 and $1.4 million 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 adjusted 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 $1.3 million and $3.2 million for the three and six months ended June 30, 2009. No amounts were recorded in the three and six months ended June 30, 2008 as the agreement with Alpharma was executed in the third quarter of 2008 and became effective in the fourth quarter of 2008. The cumulative aggregate payments received by the Company as of June 30, 2009 were $23.9 million under this agreement.

Agreement with Nycomed

In November 2006, the Company entered into a collaboration agreement (the Agreement) with Nycomed. 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 $180.0 million upon achievement of defined development, regulatory and sales milestones. The Company will jointly direct and equally fund with Nycomed a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the E.U. 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, Asia 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 expiry of patents covering POSIDUR in all major market countries in the E.U. and for adverse product events.

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 pursuant to EITF 07-1, *Accounting for Collaborative Arrangements*. 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 the Company but reimbursable by Nycomed under the terms of the Company s agreement with Nycomed were $855,000 and $2.0 million in the three and six months ended June 30, 2009, respectively, compared to $904,000 and $1.7 million for the corresponding periods in 2008, which are accounted for as a reduction of research and development expenses. Research and development expenses for POSIDUR incurred by Nycomed but reimbursable by the Company under the terms of its agreement with Nycomed were $1.1 million and $2.1 million in the three and six months ended June 30, 2009, respectively, compared to $784,000 and $1.1 million for the corresponding periods in 2008, which are accounted for as additional research and development expenses. Both parties bear 50% of the development expenses under the collaboration agreement for POSIDUR. The Company recognized $381,000 and $763,000 for the three and six months ended June 30, 2009, compared to $763,000 and $1.5 million for the corresponding periods in 2008, respectively, as collaborative research and development revenue from the amortization of the $14.0 million upfront fee received in 2006. The Company s estimate of the remaining term of its continuing involvement was adjusted in the first quarter of 2009 as a result of an updated development plan for POSIDUR in Europe. The cumulative aggregate payments received by the Company from Nycomed as of June 30, 2009 were $33.0 million under this agreement. In addition, the cumulative aggregate payments paid by the Company to Nycomed were $4.7 million as of June 30, 2009.

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. In February 2009, Endo notified the Company that it was terminating the license agreement with the Company, and thereby returning to the Company Endo s right to develop and commercialize TRANSDUR-Sufentanil in the U.S. and Canada effective August 26, 2009. Endo has been assisting in an orderly and rapid transition of this program back to DURECT.

The $10.0 million upfront fee was 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 adjusted 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 amortization of the $10.0 million upfront fee for the three and six months ended June 30, 2009, compared to $547,000 and $1.1 million for the corresponding periods in 2008, respectively. The $10.0 million upfront fee from Endo has been fully amortized as of June 30, 2009. Total collaborative research and development revenue recognized under this arrangement was zero and $985,000 for the three and six months ended June 30, 2009, compared to

$836,000 and $1.6 million for the corresponding periods in 2008, respectively. The cumulative aggregate payments received by the Company as of June 30, 2009 were $21.5 million under this agreement.

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Agreement with Pain Therapeutics, Inc.

In December 2002, the Company entered into an exclusive agreement with Pain Therapeutics, Inc. (Pain Therapeutics) to develop and commercialize on a worldwide basis Remoxy and other oral sustained release, abuse deterrent opioid products incorporating four specified opioid drugs, using the ORADUR technology. 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, the Company is eligible to receive milestone payments of up to $9.3 million in the aggregate upon the achievement of predetermined development and regulatory milestones for the four drug candidates currently in development. As of June 30, 2009, the Company has received $1.7 million in 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 agreements with Pain Therapeutics was $46,000 and $322,000 for the three and six months ended June 30, 2009, compared to $1.9 million and $4.0 million for the corresponding periods in 2008, respectively. The cumulative aggregate payments received by the Company from Pain Therapeutics as of June 30, 2009 were $31.1 million under this agreement.

During 2008, the Company began to manufacture commercial lots of certain key components 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. The Company deferred recognizing zero and $1.7 million of product revenue for the three and six months ended June 30, 2009 related to its shipments to King of key components that are included in Remoxy pending the execution of a final supply agreement with King. The cumulative aggregate deferred revenue related to these key components as of June 30, 2009 was $3.0 million.

In March 2009, King assumed the responsibility for further development of Remoxy from Pain Therapeutics. As a result of this change, the Company shall continue 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.

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Agreement with EpiCept Corporation

In December 2006, the Company entered into a license agreement with EpiCept which provided the Company with the exclusive, worldwide rights to certain of EpiCept s intellectual property for a transdermal patch containing bupivacaine for the treatment of back pain. Pursuant to the agreement, the Company paid EpiCept a $1.0 million upfront fee in 2006 and subject to the Company s achievement of specified milestones, agreed to pay EpiCept an additional $9.0 million in milestone payments as well as an undisclosed royalty on net sales of any product covered by the license. The $1.0 million fee was recognized as research and development expense at the execution of the agreement since the rights purchased had not yet reached technological feasibility and such rights also had no future alternative uses.

In September 2008, the Company and EpiCept entered into an amendment to the license agreement. Under the amendment, among other changes, the scope of the license was broadened from the treatment of back pain to all uses covered by the EpiCept intellectual property including myofascial pain and muscle tension pain, and the license was converted to an exclusive, worldwide, fully paid up, royalty-free, perpetual and irrevocable license. In consideration of this amendment, the Company made a one-time payment of $2.25 million to EpiCept in full satisfaction of all future payment obligations to EpiCept under the license agreement. The Company recorded the payment of $2.25 million as a research and development expense in the third quarter of 2008 since the rights purchased had not yet reached technological feasibility and such rights also had no future alternative uses. No expenses under this agreement have been recorded for the three and six months ended June 30, 2009 and the corresponding periods in 2008.

Agreement with ALZA Corporation

In April 1998, the Company entered into a development and commercialization agreement with ALZA, which has been subsequently amended and restated, most recently in October 2002. The agreement provides the Company with exclusive rights to develop, commercialize and manufacture products using ALZA s patented DUROS® technology in selected fields of use, and obligates the Company to pay ALZA a royalty on the net sales of the Company s DUROS-based products and a percentage of upfront license fees, milestone payments, or any other payments or consideration received by the Company with respect to such DUROS-based products. In connection with the execution of the Agreement, the Company issued 5,600,000 shares of Series A-1 preferred stock, which were subsequently converted into 5,600,000 shares of common stock concurrent with the Company s initial public offering in 2000. The Company issued an additional 1,000,000 shares of its common stock and a warrant to purchase 1,000,000 shares of its common stock to ALZA in connection with an amendment of the Agreement in April 2000. The Company recorded the fair value of the common stock and the warrant in the amount of $13.5 million as additional paid-in capital and as a contra-equity account referred to as deferred royalties and commercial rights. The warrant expired in September 2004. At the end of 2008, the Company made the strategic decision that other research and development programs would take priority over CHRONOGESIC and recorded a $13.5 million non-cash write down of deferred royalties and commercial rights associated with CHRONOGESIC given the fact that there are no plans in the foreseeable future to actively attempt to develop CHRONOGESIC. This agreement can be terminated by either party for material breach by the other party and by the Company without cause.

Note 3. Fair Value Measurements

SFAS No. 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and enhances disclosures about fair value measurements. Fair value is defined under SFAS No. 157 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. Valuation techniques used to measure fair value under SFAS No. 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes 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.

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The financial instruments are valued using quoted prices in active markets or based upon other observable inputs. The following table sets forth the fair-value of the Company s financial assets that were measured on a recurring basis as of June 30, 2009 (in thousands):

	Level 1	Level 2	Level 3	Total
Money market funds	$	$ 5,437	$	$ 5,437
Certificates of deposit		428		428
Commercial paper		12,358		12,358
Corporate debts		5,695		5,695
U.S. Government agencies		15,954		15,954
Total	$	$ 39,872	$	$ 39,872

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, we believe the potential differences in the estimate of fair value for the Company s available-for-sale securities are immaterial.

The following is a summary of available-for-sale securities (in thousands):

	June 30, 2009			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 5,437	$	$	$ 5,437
Certificates of deposit	428			428
Commercial paper	12,356	5	(3)	12,358
Corporate debts	5,672	23		5,695
U.S. Government agencies	15,926	29	(1)	15,954
	$ 39,819	$ 57	$ (4)	$ 39,872
Reported as:				
Cash and cash equivalents	$ 8,036	$ 1	$	$ 8,037
Short-term investments	24,472	39	(4)	24,507
Short-term restricted investments	372			372
Long-term investments	6,511	17		6,528
Long-term restricted investments	428			428
	$ 39,819	$ 57	$ (4)	$ 39,872

	December 31, 2008			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$ 22,092	$	$	$ 22,092
Certificates of deposit	425			425
Commercial paper	8,705	11		8,716
Corporate debts	6,363	31	(16)	6,378

U.S. Government agencies	12,471	55		12,526
	$ 50,056	$ 97	$ (16)	$ 50,137
Reported as:				
Cash and cash equivalents	$ 26,884	$ 6	$	$ 26,890
Short-term investments	20,745	91		20,836
Short-term restricted investments	624			624
Long-term investments	1,378		(16)	1,362
Long-term restricted investments	425			425
	$ 50,056	$ 97	$ (16)	$ 50,137

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The following is a summary of the cost and estimated fair value of available-for-sale securities at June 30, 2009, by contractual maturity (in thousands):

	2009	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$ 33,308	$ 33,344
Mature after one year through five years	6,511	6,528
	$ 39,819	$ 39,872

During the three and six months ended June 30, 2009 and 2008, 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 June 30, 2009 (in thousands):

	Unrealized Loss for Less than 12 Months	
	Fair Value	Unrealized Loss
Commercial paper	$ 4,567	$ (3)
U.S. Government agencies	3,263	(1)
	$ 7,830	$ (4)

The following is a summary of unrealized losses for available-for-sale securities at December 31, 2008 (in thousands):

	Unrealized Loss for Less than 12 Months	
	Fair Value	Unrealized Loss
Corporate debts	$ 2,361	$ (16)

There were no securities that have had an unrealized loss for more than 12 months as of June 30, 2009 and December 31, 2008.

To date the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value. The Company recognizes an impairment charge when the decline in the estimated fair value of a marketable security below the amortized cost is determined to be other-than-temporary. The Company considers various factors in determining whether to recognize an impairment charge, including the duration of time and the severity to which the fair value has been less than our amortized cost, any adverse changes in the investees financial condition and our intent and ability to hold the marketable security for a period of time sufficient to allow for any anticipated recovery in market value.

Note 4. Stock-Based Compensation

As of June 30, 2009, the Company has five stock-based employee compensation plans, which have not changed in 2008 or 2009. The employee stock-based compensation cost that has been included in the statements of operations was $2.3 million and $5.8 million for the three and six months ended June 30, 2009, compared to $2.1 million and $4.5 million for the corresponding periods in 2008, respectively.

As of June 30, 2009 and December 31, 2008, $88,000 and $87,000, respectively, of stock-based compensation cost was capitalized in inventory on the Company s balance sheets.

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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 and six months ended June 30, 2009 and 2008:

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Stock options				
Risk-free rate	2.36-2.87%	3.19-3.55%	1.98-2.87%	2.67-3.55%
Expected dividend yield				
Expected life of option (in years)	6	6	6	6
Volatility	85-87%	82-83%	84-87%	81-83%

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Employee Stock Purchase Plan				
Risk-free rate	0.31-3.95%	1.73-3.95%	0.31-3.95%	1.73-3.95%
Expected dividend yield				
Expected life of option (in years)	1.25	1.25	1.25	1.25
Volatility	51-150%	51-61%	51-150%	51-61%

Note 5. Reduction in Force

In March 2009, the Company reduced the size of its California workforce by 41 employees or approximately 24% of its headcount. The goal of this action was to better align its cost structure with anticipated revenues and operating expenses, while not compromising the Company s key corporate objectives for the year. The Company substantially completed this headcount reduction during the first quarter of 2009, and incurred approximately $443,000 in severance costs for the impacted employees, of which approximately $16,000 was paid in the first quarter of 2009. Accrued severance costs were approximately $427,000 as of March 31, 2009, all of which were paid in April 2009.

As of June 30, 2009, the Company had 126 employees, including 75 in research and development, 22 in manufacturing and 29 in selling, general and administrative.

Note 6. Accrued Asset Retirement Obligation

In accordance with SFAS No. 143 *Accounting for Asset Retirement Obligations,* the Company recorded $383,000 in the three months ended June 30, 2009 as a liability on its balance sheet for an asset retirement obligation associated with the estimated restoration cost recorded for one of its buildings whose lease recently expired. The charge to record these costs was classified as research and development expense and general and administration expense of $285,000 and $98,000, respectively, in the Company s statements of operations for the three months ended June 30, 2009.

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ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management s Discussion and Analysis of Financial Condition and Results of Operations for the three and six months ended June 30, 2009 and 2008 should be read in conjunction with our annual report on Form 10-K 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;
- the progress and results of our research and development programs;
- 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 the FDA and other government regulation on our business;
- uncertainties associated with obtaining, maintaining 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; and
- future performance, sufficiency of our cash resources, anticipated capital requirements and our need for additional financing.

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of such forward looking statements and the potential risks and uncertainties that may impact upon their accuracy, see the Risk Factors section and Overview section of this Management s Discussion and Analysis of Financial Condition and Results of Operations. These forward-looking statements reflect our view only as of the date of this report. We undertake no obligations to update any forward-looking statements. You should also carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission.

Overview

We are 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.

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.

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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 six disclosed on-going product candidates in development. The following are our publicly announced product candidates in development:

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 November 2006, we entered into a collaboration agreement with Nycomed Danmark, APS. Under the terms of the agreement, we licensed to Nycomed the exclusive commercialization rights to POSIDUR for the European Union (E.U.) and certain other countries. Nycomed paid us an upfront license fee of $14.0 million in 2006 and an $8.0 million milestone payment in 2007, with future potential additional milestone payments of up to $180.0 million upon achievement of defined development, regulatory and sales milestones. We jointly direct and equally fund with Nycomed a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the E.U. In addition, we will manufacture and supply the product to Nycomed for commercial sale in the territory licensed to Nycomed. Nycomed will pay us blended royalties on sales in the defined territory of 15-40% depending on annual sales, as well as a manufacturing markup. We retain full commercial rights to POSIDUR in the U.S., Canada, Asia and certain other countries.

In 2007, we successfully completed a 122 patient Phase IIb clinical trial of POSIDUR for treatment of post-operative pain in patients undergoing inguinal hernia repair. In the Phase IIb trial, POSIDUR at a dose of 5 mL demonstrated statistically significant reductions in pain and in total consumption of supplemental opioid analgesic medications versus placebo. These successful results triggered the $8.0 million milestone payment by Nycomed to us under our agreement with Nycomed.

In the first quarter of 2009, we received detailed feedback from the FDA on our proposed Phase III program. We are pursuing a target label for POSIDUR that would allow POSIDUR to be used for a broad range of surgeries. Based on FDA feedback, we anticipate conducting one pivotal efficacy study and several other supportive clinical studies in additional surgical models to provide greater definition for the settings in which the product should be used and to support our target label. We currently expect that the total number of patient exposures that we will submit to the FDA in an NDA will be approximately 700-800. Under our current development program, over 300 human subjects have been exposed to POSIDUR. Assuming the program progresses as we expect, we anticipate that the Phase III program should take approximately two years from initiation to NDA filing. Our major on-going clinical activities for POSIDUR are as follows:

We are conducting an approximately 60 patient Phase IIb clinical study in shoulder surgery and expect to have data from that study in 2009.

Nycomed is conducting a Phase IIb study in hysterectomy patients and a Phase IIb study in shoulder surgery patients. Those studies will be conducted in a different manner than U.S. studies and will be suitable for European regulatory approval purposes. We anticipate that these studies will provide data from an additional surgical model (hysterectomy) and will add to our safety database.

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

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

In December 2007, Pain Therapeutics and King reported positive results from the pivotal Phase III trial submitted under an approved Special Protocol Assessment (SPA) with the FDA. The NDA was submitted to the FDA in June 2008, and in August 2008 the NDA was accepted by the FDA and granted priority review. In December 2008, Pain Therapeutics received a Complete Response Letter for its NDA for Remoxy in which the FDA determined that the NDA was not approved. According to Pain Therapeutics, the FDA indicated that additional

non-clinical data will be required to support the approval of Remoxy, but the FDA has not requested or recommended additional clinical efficacy studies prior to approval. King Pharmaceuticals, the commercialization partner of Pain Therapeutics for Remoxy, assumed responsibility for further development of Remoxy from Pain Therapeutics in March 2009. Since that time, we continued to perform development activities in support of the Remoxy NDA filing in accordance with the terms and conditions of the Development and License Agreement between us and Pain Therapeutics but with King substituted in lieu of Pain Therapeutics with respect to our performance of those activities. On July 2, 2009, King met with the FDA to discuss the Complete Response Letter. According to King and Pain Therapeutics, the outcome of that meeting provided King with a clear path forward to resubmit the REMOXY NDA and to address all FDA comments in the Complete Response Letter. According to the King

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Pharmaceuticals / Pain Therapeutics press release dated July 7, 2009, King now anticipates the resubmission of the NDA could occur mid-year 2010. King has stated that it remains committed to the development and commercialization of REMOXY and looks forward to working closely with the FDA toward approval of the product.

During 2008, we began to manufacture commercial lots of certain key components 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 we made shipments of these materials to meet the production requirements of King, which has rights to commercialize Remoxy upon approval by the FDA. Revenue attributable to these key components aggregating $1.7 million and cost of goods sold aggregating $1.5 million in the six months ended June 30, 2009 has been deferred pending the execution of a final supply agreement with King Pharmaceuticals. The cumulative aggregate deferred revenue attributable to the shipment to King of these key components was $3.0 million, and the cumulative aggregate deferred cost of goods sold was $2.0 million as of June 30, 2009.

We have also worked with King and Pain Therapeutics on the development of ORADUR-based abuse-resistant opioid drug candidates in addition to Remoxy. Phase I clinical trials have been completed for two of these ORADUR-based drug candidates. According to Pain Therapeutics, the data from these Phase I trials indicate that these drug candidates are safe and well-tolerated with a release profile that appears well suited to use with a chronic pain population. The active ingredients in these two drug candidates are opioids whose identities have not been publicly disclosed.

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 1/5th the size of currently marketed transdermal fentanyl patches for a therapeutically equivalent dose) may offer improved convenience and compliance for patients. In 2005, DURECT successfully completed a Phase II clinical trial of TRANSDUR-Sufentanil in chronic pain.

In March 2005, we entered into an agreement with Endo granting Endo exclusive rights to develop, market and commercialize TRANSDUR-Sufentanil in the U.S. and Canada. We received an initial payment of $10.0 million in connection with the execution of the Agreement. In February 2009, Endo notified us that it was terminating the license agreement, and thereby returning to us Endo s right to develop and commercialize TRANSDUR-Sufentanil in the U.S. and Canada effective August 26, 2009. Endo has been assisting in an orderly and rapid transition of this program back to DURECT. Effective August 26, 2009, we will hold worldwide commercialization rights for TRANSDUR-Sufentanil.

In 2008, Endo successfully completed a Phase II trial for TRANSDUR-Sufentanil in which they evaluated the conversion of patients on oral and transdermal opioids to TRANSDUR-Sufentanil. This Phase II study met its primary and secondary objectives of establishing a successful dose-titration regimen and dose potency relationships, demonstrating safety and tolerability at the therapeutic dose, and achieving effective analgesic pain control. The Phase II data, extensive non-clinical data that had been generated by Endo and detailed proposed protocols for Phase III were reviewed with the FDA at an end-of-Phase II meeting on February 19, 2009. As a result of that meeting, we believe we understand the anticipated regulatory pathway for the Phase III program and approval, which will follow a 505(b)2 pathway as discussed with FDA. This pathway would allow us to reference third-party data, potentially reducing time and expense. We are now in active discussions with multiple parties regarding licensing of the program.

ELADUR (TRANSDUR -Bupivacaine)

Our transdermal bupivacaine patch (ELADUR) uses our proprietary TRANSDUR transdermal technology and is intended to provide continuous delivery of bupivacaine for up to three days from a single application, as compared to a wearing time limited to 12 hours with currently available lidocaine patches.

In 2007, we successfully completed a 60 patient Phase IIa clinical trial for ELADUR. In this study of patients suffering from post-herpetic neuralgia, ELADUR showed improved pain control versus placebo during the 3-day continuous treatment period. In addition, ELADUR appeared well tolerated overall, and patients treated with ELADUR and placebo exhibited similar safety profiles. During 2008, we continued to develop our clinical and regulatory strategy, and to conduct manufacturing scale-up and processing activities to secure additional Phase II and Phase III supplies. In June 2008, the FDA granted to us orphan drug designation for bupivacaine for relief of persistent pain associated with post-herpetic neuralgia (PHN). If ELADUR is the first bupivacaine product approved for PHN, under the 1983 Orphan Drug Act, ELADUR will receive seven years of market exclusivity following the approval of the product by the FDA. There can be no assurance that ELADUR will be the first bupivacaine product approved for PHN, and therefore ELADUR may not be entitled to the seven year exclusivity for orphan drugs.

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In September 2008, we entered into a development and license agreement with Alpharma granting Alpharma the exclusive worldwide rights to develop and commercialize ELADUR. The agreement became effective in October 2008 after clearance under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976. Under the terms of the agreement, upon closing of the transaction, 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. Our main activities since December 2008 have involved interacting with the King team on details associated with next steps in the clinical program, which King expects to initiate this year.

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 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 attention deficit/hyperactivity disorder. Another area of focus includes 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.

Collaborative Research and Development Revenues

Collaborative research and development revenues consist of three broad categories: (a) the amortization of upfront license payments on a straight-line basis over the period of our continuing involvement with the third party, (b) the reimbursement of qualified research expenses by third parties, and (c) milestone payments in connection with our collaborative agreements. During the last several years, we generated collaborative research and development revenues from collaborative agreements related to TRANSDUR-Sufentanil (collaboration with Endo), Remoxy and other specified ORADUR-based oral opioids (collaboration with Pain Therapeutics), POSIDUR (collaboration with Nycomed), ELADUR (collaboration with Alpharma) and several feasibility agreements. In contrast to our other collaborations, due to the terms and nature of the Nycomed collaboration, we do not recognize revenue from the reimbursement of qualified research expenses by Nycomed pursuant to EITF 07-1, *Accounting for Collaborative Arrangements*. Rather, we record research and development expense equal to our net share of the joint research and development expenses undertaken under the product development plan.

Product Revenues

We currently generate product revenue from the sale of two product lines:

ALZET® osmotic pumps for animal research use; and

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

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.

Reduction in force

In March 2009, we reduced the size of our California workforce by 41 employees or approximately 24% of our headcount. The goal of this action was to better align our cost structure with anticipated revenues and operating expenses, while not compromising our key corporate objectives for the year. We substantially completed this headcount reduction during the first quarter of 2009, and incurred approximately $443,000 in severance costs for the impacted employees, of which approximately $16,000 was paid in the first quarter of 2009. Accrued severance costs were approximately $427,000 as of March 31, 2009, all of which were paid in April 2009.

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Operating results

Since our inception in 1998, we have had a history of operating losses. At June 30, 2009, we had an accumulated deficit of $299.8 million and our net losses were $7.5 million and $16.2 million for the three and six months ended June 30, 2009. Our net losses were $43.9 million, $24.3 million and $33.3 million for the twelve months ended December 31, 2008, 2007 and 2006, 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 nonclinical studies, clinical trials and other research and development activities as well as to incur additional stock-based compensation costs related to research and development personnel under SFAS 123(R). 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 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 exists, the price is fixed or determinable and the collectibility of the amounts owed is reasonably assured. We recognize revenue from the sale of our products and license and collaboration agreements pursuant to Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force (EITF) Issue 00-21 *Revenue Arrangements with Multiple Deliverables*. Multiple element agreements entered into are evaluated under the provision of EITF 00-21. We evaluate 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), 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 collectibility 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 EITF Issue 07-1 (EITF 07-1), *Accounting for 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.

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.

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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.

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, while acquired in-process research and development is recorded as a one-time charge on the acquisition date. Acquired in-process research and development represents the value of research projects in process at the time of acquisition which have not yet reached technological feasibility and which have no alternative future use. The determination of the amount of acquired in-process research and development involves several estimates and judgments, including the percentage of completion of the in-process technology and assumptions about future cash flows to be derived from the technology and discount rates. Different assumptions employed in determining the value of in-process research and development could result in a greater or lesser amount being recorded.

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:

- 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 SFAS 142, Goodwill and Other Intangible Assets. No impairment of goodwill has been recorded through December 31, 2008. However, there can be no assurance that at the time other periodic reviews are completed, a material impairment charge will not be recorded.

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 the project status. If these good faith estimates are inaccurate, actual expenses incurred could materially differ from our estimates.

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Stock-Based Compensation

Under the provisions of FAS 123(R), Share Based Payment (FAS 123R), 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 SFAS 123(R) and SAB 107. 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. SFAS 123(R) 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.

Recent Accounting Pronouncements

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*. This standard replaces SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, and establishes only two levels of U.S. generally accepted accounting principles (GAAP), authoritative and nonauthoritative. The FASB Accounting Standards Codification (the Codification) will become the single source for all authoritative GAAP recognized by the FASB. All other non-grandfathered, non-SEC accounting literature not included in the Codification will become nonauthoritative. This standard is effective for financial statements for interim or annual reporting periods ending after September 15, 2009. We will begin to use the new guidelines and numbering system prescribed by the Codification when referring to GAAP in the third quarter of 2009. As the Codification was not intended to change or alter existing GAAP, it will not have any impact on our financial statements.

In May 2009, the FASB issued SFAS No. 165, Subsequent Events (SFAS No. 165). This standard modifies the names of the two types of subsequent events either as recognized subsequent events (previously referred to in practice as Type I subsequent events) or non-recognized subsequent events (previously referred to in practice as Type II subsequent events). In addition, the standard modifies the definition of subsequent events to refer to events or transactions that occur after the balance sheet date, but before the financial statements are issued (for public entities) or available to be issued (for nonpublic entities). It also requires the disclosure of the date through which subsequent events have been evaluated. The Company began applying the provisions of SFAS No.165 in the second quarter of 2009 and its adoption did not impact the Company s financial statements, other than the disclosures required by SFAS No. 165. See Note 1 for additional disclosures pursuant to SFAS No. 165.

In April 2009, the FASB issued three Staff Positions (FSP) that were intended to provide additional application guidance and enhanced disclosures regarding fair value measurements and impairments of securities. FSP No. 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*, provides additional guidelines for estimating fair value in accordance with SFAS No. 157, *Fair Value Measurements.* FSP No. 115-2, *Recognition and Presentation of Other-Than-Temporary Impairments*, changes existing accounting requirements for other-than-temporary-impairment (OTTI) for debt securities by replacing the current requirement that a holder have the positive intent and ability to hold an impaired security to recovery in order to conclude an impairment was temporary with a requirement that an entity conclude it does not intend to sell an impaired security and it will not be required to sell the security before the recovery of its amortized cost basis. FSP No. 107-1 and Accounting Principles Board (APB) Opinion No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments*, increases the frequency of fair value disclosures. These FSPs are effective for fiscal years and interim periods ended after June 15, 2009. We adopted these FSPs in the second quarter of 2009 and our adoption did not have any impact on our financial statements.

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In May 2008, the FASB issued Staff Position No APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement) (FSP APB 14-1). FSP APB 14-1 requires the issuer of certain convertible debt instruments that may be settled in cash or other assets on conversion, either in part or in full, to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that results in the recognition of interest expense equal to the issuer s nonconvertible debt borrowing rate. This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. This FSP must be applied retrospectively to all periods presented. The adoption of FSP APB 14-1 did not have an impact on our financial statements.

In February 2008, the FASB issued FASB Staff Position No. FSP 157-2, Effective Date of FASB Statement No. 157 , which provides a one year deferral of the effective date of SFAS 157 for non-financial assets and non-financial liabilities, except for those items that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, on January 1, 2008, we adopted provisions of SFAS 157 with respect to its financial assets and liabilities. On January 1, 2009, we adopted the provisions of FSP 157-2 for its non-financial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis. These include goodwill and other non-amortizable intangible assets. The adoption of FSP 157-2 did not have an impact on our financial statements.

In December 2007, the Emerging Issues Task Force of the FASB issued a consensus on Issue No. 07-1 (EITF 07-1), *Accounting for Collaborative Arrangements.* The scope of EITF 07-1 is limited to collaborative arrangements where no separate legal entity exists and in which the parties are active participants and are exposed to significant risks and rewards that depend on the success of the activity. The Task Force concluded that revenue transactions with third parties and associated costs incurred should be reported in the appropriate line item in each company s financial statements pursuant to the guidance in EITF 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. The Task Force also concluded that the equity method of accounting under Accounting Principles Board Opinion 18, *The Equity Method of Accounting for Investments in Common Stock*, should not be applied to arrangements that are not conducted through a separate legal entity. The Task Force also concluded that the income statement classification of payments made between the parties in an arrangement should be based on a consideration of the following factors: the nature and terms of the arrangement; the nature of the entities operations; and whether the parties payments are within the scope of existing GAAP. To the extent such costs are not within the scope of other authoritative accounting literature, the income statement characterization for the payments should be based on an analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. The provisions of EITF 07-1 are effective for fiscal years beginning on or after December 15, 2008, and companies are required to apply the provisions through retrospective application to all collaborative arrangements existing at adoption as a change in accounting principle. The adoption of EITF 07-1 did not have an impact on our financial statements.

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Results of Operations

Three and six months ended June 30, 2009 and 2008

Revenues. Net revenues were $4.9 million and $11.0 million for the three and six months ended June 30, 2009, compared to $6.3 million and $12.7 million for the corresponding periods in 2008, respectively. The decrease in total revenues in the three and six months ended June 30, 2009 is primarily attributable to lower collaborative research and development revenue recognized from our agreements with Pain Therapeutics, Endo and Nycomed, partially offset by higher collaborative research and development revenue from King.

Collaborative research and development and other revenue

We recognize revenues from collaborative research and development activities and service contracts. We recorded $2.6 million and $6.4 million of collaborative research and development revenue for the three and six months ended June 30, 2009 compared to $3.9 million and $8.1 million for the corresponding periods in 2008. 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 amortization of upfront fees. The decrease in collaborative research and development revenue in the three months ended June 30, 2009 was primarily attributable to lower revenue recognized in connection with our agreement for Remoxy and other ORADUR-based opioid drug candidates (collaboration with Pain Therapeutics), our agreement for TRANSDUR-Sufentanil (collaboration with Endo) and amortization of the upfront payment for POSIDUR (collaboration with Nycomed), partially offset by higher collaborative research and development revenue recognized in connection with our agreement for ELADUR (collaboration with King) and from certain feasibility agreements compared with the same period in 2008. The decrease in collaborative research and development revenue in the six months ended June 30, 2009 was primarily attributable to lower revenue recognized in connection with our agreement with Pain Therapeutics for Remoxy and other ORADUR-based opioid drug candidates, lower revenue and the end of the amortization of an up-front payment from Endo for our agreement for TRANSDUR-Sufentanil, reduced amortization of the upfront payment for POSIDUR, and lower revenue from certain feasibility agreements, partially offset by higher collaborative research and development revenue recognized in connection with our agreement for ELADUR compared with the same period in 2008.

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 and six months ended June 30, 2009, we recognized zero and $875,000, respectively, in collaborative research and development revenue related to this upfront fee, compared to $547,000 and $1.1 million for the corresponding periods in 2008. 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 has been fully amortized as of June 30, 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 and six months ended June 30, 2009, we recognized $381,000 and $763,000, respectively, in collaborative research and development revenue related to this upfront fee, compared to $763,000 and $1.5 million for the corresponding periods in 2008. Our estimate of the remaining term of our continuing involvement was adjusted in the first quarter of 2009 as a result of an updated development plan for POSIDUR in Europe.

We also received a $20.0 million upfront fee in connection with the development and license agreement signed with Alpharma 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 with respect to ELADUR. For the three and six months ended June 30, 2009, we recognized $804,000 and $1.8 million, respectively, in collaborative research and development revenue related to this upfront fee, compared to zero for the corresponding periods in 2008. Our estimate of the remaining term of our continuing involvement was adjusted in the second quarter of 2009 as a result of an updated development plan for ELADUR.

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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 revenues associated with our major collaborators are as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Collaborator				
King Pharmaceuticals, Inc. (King)(1)	$ 1,632	$	$ 3,556	$
Endo Pharmaceuticals, Inc. (Endo)(2)		836	985	1,634
Nycomed Danmark, APS (Nycomed)(3)	381	763	763	1,525
Pain Therapeutics, Inc. (Pain Therapeutics)	46	1,861	322	4,009
Others	547	407	725	968
Total collaborative research and development and other revenue	$ 2,606	$ 3,867	$ 6,351	$ 8,136

Notes:

(1) Amounts related to amortization of upfront fees were $804,000 and $1.8 million for the three and six months ended June 30, 2009, respectively, compared to zero for each of the corresponding periods in 2008.

(2) Amounts related to amortization of upfront fees were zero and $875,000 for the three and six months ended June 30, 2009, respectively, compared to $547,000 and $1.1 million for the corresponding period in 2008. Our agreement with Endo will terminate effective August 26, 2009.

(3) Amounts related to amortization of upfront fees were $381,000 and $763,000 for the three and six months ended June 30, 2009, respectively, compared to $763,000 and $1.5 million for the corresponding periods in 2008. 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.

We amortize 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.

Revenues from service contracts revenues were $30,000 in the three and six months ended June 30, 2009, compared to $17,000 and $49,000 for the corresponding periods in 2008. Service contract revenues recognized were related to certain polymer related service contracts we signed with various customers. We currently do not expect to increase our effort to generate significant revenue from our service contracts related to our polymer business in the future.

Product revenue

A portion of our revenues is derived from our product sales, which include our ALZET mini pump product line, and to a lesser extent our LACTEL biodegradable polymer product line. Net product revenues were $2.3 million and $4.7 million in the three and six months ended June 30, 2009, respectively, compared to $2.4 million and $4.6 million for the corresponding periods in 2008. The decrease in the three months ended June 30, 2009 were primarily due to lower product revenue from our ALZET mini pump product line as a result of lower units sold, partially offset by higher product revenue from our LACTEL polymer product line as a result of higher units sold. The increase in the six months ended June 30, 2009 were primarily due to higher product revenue from our LACTEL polymer product line as a result of higher units sold, partially offset by lower revenue from our ALZET mini pump product line as a result of lower units sold.

We deferred recognizing zero and $1.7 million of product revenue for the three and six months ended June 30, 2009 related to our shipments to King of key components that are included in Remoxy pending the execution of a final supply agreement with King. The cumulative aggregate deferred revenue related to these key components as of June 30, 2009 was $3.0 million.

Cost of revenues. Cost of revenues was $837,000 and $1.7 million for the three and six months ended June 30, 2009, respectively, compared to $982,000 and $1.8 million for the corresponding periods in 2008. The decrease in the cost of product revenue in the three and six months ended June 30, 2009 was primarily the result of lower units sold from our ALZET mini pump product line and improved manufacturing efficiency 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. Cost of service contract revenue was $1,000 for the three and six months ended June 30, 2009, respectively, compared to $4,000 and $19,000 for the corresponding periods in 2008. Stock based compensation expense recognized under SFAS 123(R) related to cost of revenues was $117,000 and $195,000 for the three and six months ended June 30, 2009, respectively, compared to $31,000 and $66,000 for the corresponding periods in 2008.

We deferred recognizing zero and $1.5 million of cost of goods sold related to our shipments to King of key components that are included in Remoxy for the three and six months ended June 30, 2009 pending the execution of a final supply agreement with King. The cumulative aggregate deferred cost of goods sold related to these key components was $2.0 million as of June 30, 2009.

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As of June 30, 2009 and 2008, we had 22 and 32 manufacturing employees, respectively. The decrease in 2009 was due to the lower number of employees involved in commercial manufacturing of certain excipients that are components of Remoxy.

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 $7.9 million and $17.8 million for the three and six months ended June 30, 2009, respectively, compared to $9.9 million and $19.5 million for the corresponding periods in 2008. Excluding the impact of stock-based compensation expenses, research and development expenses decreased by $2.0 million and $2.4 million in the three and six months ended June 30, 2009 compared to the corresponding periods in 2008. The decreases in the three and six months ended June 30, 2009 were primarily attributable to lower development costs associated with ELADUR, Remoxy and other select ORADUR-based opioid drug candidates and our biologics programs, partially offset by higher development costs associated with POSIDUR and other research programs compared to the corresponding periods in 2008 as more fully discussed below. Stock-based compensation expense recognized under SFAS 123(R) related to research and development personnel was $1.3 million and $3.6 million for the three and six months ended June 30, 2009, respectively, compared to $1.4 million and $3.0 million for the corresponding periods in 2008.

POSIDUR

Our research and development expenses for POSIDUR increased to $2.9 million and $6.4 million in the three and six months ended June 30, 2009 from $2.5 million and $4.3 million in the corresponding periods in 2008 due to higher costs associated with clinical trial expenses and contract manufacturing development activities. Research and development expenses for POSIDUR incurred by us but reimbursable by Nycomed under the terms of our agreement with Nycomed were $855,000 and $2.0 million in the three and six months ended June 30, 2009, respectively, compared to $904,000 and $1.7 million for the corresponding periods in 2008, which are 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 $1.1 million and $2.1 million in the three and six months ended June 30, 2009, respectively, compared to $784,000 and $1.1 million for the corresponding periods in 2008, which are accounted for as additional research and development expenses. As a result of the collaboration agreement with Nycomed, our research and development expenses were increased by $291,000 and $124,000 in the three and six months ended June 30, 2009, respectively, compared to a reduction of $120,000 and $590,000 for the corresponding periods in 2008. 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 defined under the collaboration agreement for POSIDUR.

ELADUR

Our research and development expenses for ELADUR decreased to $694,000 and $2.2 million in the three and six months ended June 30, 2009 from $2.3 million and $4.4 million in the corresponding periods in 2008. The decreases in 2009 were primarily due to lower employee costs and contract manufacturing expenses related to manufacturing scale-up and processing activities to secure additional clinical supplies for this product candidate.

Remoxy and other select ORADUR-based opioid products

Our research and development expenses for Remoxy and other opioids partnered with Pain Therapeutics decreased to $476,000 and $934,000 in the three and six months ended June 30, 2009 from $1.6 million and $3.5 million in the correspoding periods in 2008. The decreases were primarily due to decreased support activities for Remoxy after the filing of the Remoxy NDA as well as decreased formulation and clinical manufacturing activities for other select ORADUR-based opioid drug candidates in 2009.

Biologics Programs

Our research and development expenses for biologics programs decreased to $415,000 and $1.1 million in the three and six months ended June 30, 2009 from $1.4 million and $2.3 million in the corresponding periods in 2008. The decreases were primarily due to lower external costs and employee related costs in support of these programs in 2009.

TRANSDUR-Sufentanil

Our research and development expenses for TRANSDUR-Sufentanil increased to $353,000 and $771,000 in the three and six months ended June 30, 2009 from $314,000 and $636,000 for the corresponding periods in 2008. The increases were primarily due to increased activities

associated with transferring the program back to DURECT from Endo in 2009.

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Other DURECT Research Programs

Our research and development expenses for all other programs increased to $3.0 million and $6.4 million in the three and six months ended June 30, 2009 from $1.8 million and $4.4 million in the corresponding periods in 2008. The increases were primarily due to higher employee related costs and increased formulation and other development activities for these programs in 2009.

As of June 30, 2009, we had 75 research and development employees compared with 109 as of the corresponding date in 2008 largely as a result of the reduction in force in March 2009. We expect our research and development expenses to increase in the near future as we expect to continue to expand our nonclinical studies, clinical trials and other research and development activities.

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

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
POSIDUR (1)	$ 2,918	$ 2,491	$ 6,406	$ 4,346
ELADUR	694	2,324	2,177	4,386
Remoxy and other select ORADUR-based opioid drug candidates	476	1,618	934	3,489
Biologics Programs	415	1,396	1,072	2,308
TRANSDUR-Sufentanil	353	314	771	636
Others	3,010	1,755	6,409	4,367
Total research and development expenses (2)	$ 7,866	$ 9,898	$ 17,769	$ 19,532

(1) In the three and six months ended June 30, 2009, research and development expenses for POSIDUR incurred by us but reimbursable by Nycomed under the terms of the Company s agreement with Nycomed were $855,000 and $2.0 million, respectively, compared to $904,000 and $1.7 million for the corresponding periods in 2008, which were accounted for as a reduction of research and development expenses. In the three and six months ended June 30, 2009, research and development expenses for POSIDUR incurred by Nycomed but reimbursable by us under the terms of our agreement with Nycomed were $1.1 million and $2.1 million, respectively, compared to $784,000 and $1.1 million for the corresponding periods in 2008, which were accounted for as additional research and development expenses. Please see Note 2 Strategic Agreements for more details about the Company s agreement with Nycomed.

(2) Includes stock-based compensation expenses of $1.3 million and $3.6 million for the three and six months ended June 30, 2009, compared to $1.4 million and $3.0 million for the corresponding periods in 2008.

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 $3.8 million and $8.0 million for the three and six months ended June 30, 2009, respectively, compared to $4.1 million and $8.0 million for the corresponding periods in 2008. Excluding the impact of stock-based compensation expenses, selling, general and administrative expenses decreased by $499,000 and $528,000 in the three and six months ended June 30, 2009 compared to the corresponding periods in 2008 primarily due to lower employee and patent expenses incurred in the three and six months ended June 30, 2009. Stock-based compensation expense recognized under SFAS 123(R) related to selling, general and administrative personnel was $864,000 and $2.0 million for the three and six

months ended June 30, 2009, compared to $674,000 and $1.4 million for the corresponding periods in 2008.

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As of June 30, 2009, we had 29 selling, general and administrative personnel compared with 38 as of the corresponding date in 2008 largely as a result of the reduction in force in March 2009. We expect selling, general and administrative expenses to remain comparable in the near future.

Other Income (Expense). Interest and other income was $106,000 and $285,000 for the three and six months ended June 30, 2009, respectively, compared to $368,000 and $936,000 for the corresponding periods in 2008. The decrease in interest income was primarily the result of lower yields as well as lower average cash and investment balances during the three and six months ended June 30, 2009 compared to the corresponding periods in 2008.

Interest and other expense was $11,000 and $22,000 for the three and six months ended June 30, 2009, respectively, compared to $304,000 and $759,000 for the corresponding periods in 2008. The decreases in interest expense in the three and six months ended June 30, 2009 compared with the same periods of 2008 was primarily due to the conversion of $23.6 million in aggregate principal amount of convertible notes in the second quarter of 2008.

Liquidity and Capital Resources

We had cash, cash equivalents and investments totaling $41.9 million at June 30, 2009 compared to $52.7 million at December 31, 2008. These balances include $800,000 and $1.0 million of interest-bearing marketable securities classified as restricted investments on our balance sheets as of June 30, 2009 and December 31, 2008, respectively. The decrease in cash, cash equivalents and investments during the six months ended June 30, 2009 was primarily the result of ongoing operating expenses, partially offset by payments received from customers.

Working capital was $28.9 million and $43.4 million at June 30, 2009 and December 31, 2008, respectively. The decrease in working capital was primarily attributable to an increase in our operating expenditures in the six months ended June 30, 2009.

We used $11.0 million of cash in operating activities for the six months ended June 30, 2009 compared to $14.3 million for the corresponding period in 2008. The cash used for operations was primarily to fund operations as well as our working capital requirements. The decrease in cash used for operations was primarily attributable to the increases in accounts receivable from our third party collaborators and inventory for the six months ended June 30, 2009, partially offset by decreases in prepaid expenses, accrued liabilities and contract research liability compared to the corresponding period in 2008.

We used $8.7 million of cash for investing activities for the six months ended June 30, 2009 compared to $7.6 million received for the corresponding period in 2008. The increase in cash used in investing activities was primarily due to an increase in net purchases of short-term and long-term investments for the six months ended June 30, 2009 compared to the corresponding period in 2008.

We received $304,000 of cash from financing activities for the six months ended June 30, 2009 compared to $543,000 for the corresponding period in 2008. The decrease was primarily due to lower proceeds from exercises of stock options and purchases from our employee stock purchase plan in the six months ended June 30, 2009 compared to the corresponding period in 2008.

In June and July 2003, we completed a private placement of an aggregate of $60.0 million in convertible subordinated notes and received net proceeds of approximately $56.7 million after deducting underwriting fees of $3.0 million and related expenses of $300,000. The notes bore interest at a fixed rate of 6.25% per annum and were due on June 15, 2008. The notes were all converted to our common stock between the third quarter of 2005 and the second quarter of 2008. As of June 30, 2009, the remaining principal balance of our convertible subordinated notes was zero.

In conjunction with the acquisition of SBS in April 2001, we assumed the SBS Bonds with remaining principal payments of $1.7 million as of April 30, 2001, and an interest rate of 6.35% increasing each year up to 7.20% at maturity on November 1, 2009. As part of the acquisition agreement, we were required to guarantee and collateralize these bonds with a letter of credit of approximately $2.4 million that we secured with investments deposited with a financial institution in July 2001. Interest payments on the SBS Bonds are due semi-annually and principal payments are due annually. Principal payments on the SBS Bonds increase in annual increments from $150,000 to $240,000 over the term of the bonds until the principal is fully paid in 2009. We have an option to call the SBS Bonds at any time. On December 31, 2002, SBS was merged into DURECT and the SBS bonds were assigned to DURECT with the terms unchanged. At June 30, 2009, the remaining principal balance of the bonds was $240,000.

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, and service our debt obligations.

During the three months ended June 30, 2009, 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, 2008.

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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.

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 and long-term debt obligations. Fixed rate securities and borrowings 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 and floating rate borrowings may lead to additional interest expense if interest rates increase. 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 June 30, 2009, approximately 82% of our investment portfolio is composed of investments with original maturities of one year or less and approximately 20% of our investment portfolio matures less than 90 days from the date of purchase.

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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 June 30, 2009 by year of maturity (dollars in thousands):

	2009	2010	2011	Total
Cash equivalents:				
Fixed rate	$ 2,600	$	$	$ 2,600
Average fixed rate	0.77%			0.77%
Variable rate	$ 5,437	$	$	$ 5,437
Average variable rate	0.33%			0.33%
Short-term investments:				
Fixed rate	$ 17,696	$ 6,811	$	$ 24,507
Average fixed rate	1.01%	1.06%		1.02%
Long-term investments:				
Fixed rate	$	$ 6,528	$	$ 6,528
Average fixed rate		1.23%		1.23%
Restricted investments:				
Fixed rate	$ 800	$	$	$ 800
Average fixed rate	1.02%			1.02%
Total investment securities	$ 26,533	$ 13,339	$	$ 39,872
Average rate	0.93%	1.14%		0.99%

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 in timely providing them with material information relating to the Company, as required to be disclosed in the reports the Company files under the Exchange Act.

Changes in Internal Control Over Financial Reporting: There were no significant changes in the Company s internal control over financial reporting 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.

PART II OTHER INFORMATION

ITEM 1. *Legal Proceedings*

We are not a party to any material legal proceedings.

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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.

We or our third-party collaborators must conduct and satisfactorily complete required laboratory performance and safety testing, animal studies and clinical trials for our pharmaceutical systems 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 publicly announced development programs is as follows:

Remoxy In December 2007, Pain Therapeutics and King reported positive results from the pivotal Phase III trial submitted under an approved Special Protocol Assessment (SPA) with the FDA; the NDA was submitted to the FDA in June 2008, and in August 2008, the NDA was accepted by the FDA and granted priority review. In December 2008, Pain Therapeutics received a Complete Response Letter for its NDA for Remoxy in which the FDA determined that the NDA was not approved. According to Pain Therapeutics, the FDA indicated that additional non-clinical data will be required to support the approval of Remoxy, but the FDA has not requested or recommended additional clinical efficacy studies prior to approval. In March 2009, King assumed the responsibility for further development of Remoxy from Pain Therapeutics. In July 2009, King had a meeting with the FDA regarding the Complete Response Letter for Remoxy. According to King and Pain Therapeutics, the outcome of the meeting with the FDA provided King with a clear path forward to resubmit the

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REMOXY NDA and to address all FDA comments in the Complete Response Letter. According to the King/Pain Therapeutics press release, King now anticipates the resubmission of the NDA could occur mid-year 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 A successful Phase IIb clinical trial in hernia surgery was completed and an end-of-Phase II meeting has been held with the FDA. Based on feedback from the FDA, in order to obtain a broad surgical use label for POSIDUR, we are planning to conduct one pivotal efficacy study and several other supportive clinical studies in additional surgical models to provide greater definition for the settings in which the product should be used and to support our target label. During 2009, we are conducting a Phase IIb clinical study in approximately 60 shoulder surgery patients, and Nycomed is conducting Phase IIb studies in hysterectomy patients and shoulder surgery patients. 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.

TRANSDUR-Sufentanil Patch In February 2009, Endo notified us that it was terminating the license agreement, and thereby returning to us Endo s right to develop and commercialize TRANSDUR-Sufentanil in the U.S. and Canada. Endo has been assisting in an orderly and rapid transition of this program back to DURECT. Effective August 26, 2009, we will hold worldwide commercialization rights for TRANSDUR-Sufentanil. Endo recently successfully completed a Phase II program for TRANSDUR-Sufentanil in which they evaluated the conversion of patients on oral and transdermal opioids to TRANSDUR-Sufentanil. The most recent Phase II study met its primary and secondary objectives of establishing a successful dose-titration regimen and dose potency relationships, demonstrating safety and tolerability at the therapeutic dose, and achieving effective analgesic pain control. The Phase II data, extensive non-clinical data that had been generated by Endo and detailed proposed protocols for Phase III were reviewed with the FDA at an end-of-Phase II meeting on February 19, 2009. As a result of that meeting, we believe we understand the anticipated regulatory pathway for the Phase III program and approval, which will follow a 505(b)2 pathway as discussed with FDA. This pathway would allow us to reference third-party data, potentially reducing time and expense. 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.

ELADUR A Phase IIa clinical trial was completed and positive results were reported in the fourth quarter of 2007. In 2008, we conducted manufacturing scale-up and processing activities to secure additional Phase II and Phase III supplies, and developed our clinical and regulatory strategy for further development of this program. In September 2008, we entered into a development and license agreement with Alpharma Ireland Ltd., an affiliate of Alpharma Inc., granting such party the exclusive worldwide rights to develop and commercialize ELADUR. The agreement became effective in October 2008 upon clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR). Alpharma was acquired by King Pharmaceuticals in December 2008 and, as a result, the rights and obligations of the agreement are now controlled by King. Our main activities since December 2008 have involved interacting with the King team on details associated with next steps in the clinical program, which King expects to initiate this year. There can be no assurance that King will be able to successfully develop ELADUR to obtain marketing approval.

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 the data required for regulatory approval. 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.

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.

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The Food and Drug Administration (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.

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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 Food and Drug Administration (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 a public meeting on May 27 and 28, 2009 to allow for broader public input and participation. 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 in December 2008) 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 incorporating specified opioids, 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.

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 the agreements. We may not be able to

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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, and Alpharma (acquired by King) with respect to ELADUR, 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.

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;

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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 additional 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.

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 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.

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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 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 June 30, 2009, had an accumulated deficit of approximately $299.8 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.

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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. DURECT has 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.

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 additional ORADUR-based drug candidates) are currently purchased from a single or a limited number of outside sources. In particular, Eastman Chemicals 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 additional 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

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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 July 31, 2009, we held 57 issued U.S. patents and 337 issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have 93 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.

Under our agreement with ALZA, we must assign to ALZA any intellectual property rights relating to the DUROS system and its manufacture and any combination of the DUROS system with other components, active agents, features or processes. In addition, ALZA retains the right to enforce and defend against infringement actions relating to the DUROS system, and if ALZA exercises these rights, it will be entitled to the proceeds of these infringement actions.

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.

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 shall 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.

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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 U.S. Patent and Trademark Office 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.

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.

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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 additional 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.

Write-offs related to the impairment of long-lived assets 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 2008 and determined that goodwill was not impaired as of December 31, 2008. 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.

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 less than one year from the balance sheet date. Our long-term investments consist primarily of readily marketable debt securities with maturities beyond one year 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 June 30, 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.

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

In connection with our research and development activities and our manufacture of materials and pharmaceutical 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.

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 opioids, if approved, will compete with currently marketed oral opioids, transdermal opioids, local anesthetic patches, and 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 Pharmaceuticals, AstraZeneca, Arrow International, Tricumed, I-Flow and others. Numerous companies are applying significant resources and expertise to the problems of drug delivery and several of these are focusing or may focus on delivery of drugs to the intended site of action, including Alkermes, Pacira Pharmaceuticals, EpiCept, Innocoll, Inovio, Nektar, Focal, I-Flow, Anesiva, NeurogesX, Alexza, Cadence Pharmaceuticals, Javelin Pharmaceuticals 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.

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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.

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.

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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.

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 Global Market 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 sublicensee King Pharmaceuticals, Nycomed, Alpharma (now owned by King)) to develop and commercialize successfully the respective pharmaceutical systems they are developing;

adverse results (including adverse events) or delays in our clinical and non-clinical trials of POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy, our additional 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;

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adverse actions taken by regulatory 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;

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; and

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;

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

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

prohibiting stockholder action by written consent; and

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

ITEM 2. ***Unregistered Sales of Equity Securities and Use of Proceeds***

None

ITEM 3. ***Defaults Upon Senior Securities***

None

ITEM 4. ***Submission of Matters to a Vote of Security Holders***

On June 24, 2009, the Annual Meeting of Stockholders of DURECT Corporation was held at our offices in Cupertino, California.

An election of Class III directors was held with the following individuals being elected to our Board of Directors to serve until our annual meeting of stockholders for the year ending December 31, 2012:

James E. Brown	(72,810,895 votes for, 580,835 votes withheld)
Michael D. Casey	(71,348,996 votes for, 2,042,434 votes withheld)
Armand P. Neukermans	(72,158,463 votes for, 1,232,967 votes withheld)

Our board is composed of the elected Class III directors and the following continuing directors:

Simon X. Benito
Terrence F. Blaschke
David R. Hoffmann
Jon S. Saxe
Felix Theeuwes

The other matter voted upon and approved at the meeting and the number of affirmations, negative votes cast and abstentions with respect to such matter was as follows:

Ratification of the appointment of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2009 (72,866,446 votes in favor, 342,008 votes opposed, 182,976 votes abstaining and 0 non-votes).

ITEM 5. ***Other Information***

None

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ITEM 6. Exhibits

(a) Exhibits:

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.

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SIGNATURES

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

DURECT CORPORATION

By: /s/ JAMES E. BROWN
James E. Brown
Chief Executive Officer

Date: August 4, 2009

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

Date: August 4, 2009