DURECT CORP
Form 10-Q
August 08, 2008
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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, 2008

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 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, 2008, there were 81,769,675 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, 2008 (unaudited)	December 31, 2007 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,445	$ 37,589
Short-term investments	10,859	19,710
Accounts receivable (net of allowances of $47 and $49, respectively)	3,080	3,622
Inventories	2,653	1,963
Prepaid expenses and other current assets	1,723	1,904
Total current assets	49,760	64,788
Property and equipment, net	6,988	7,658
Goodwill	6,399	6,399
Intangible assets, net	182	180
Long-term investments	4,259	3,697
Restricted investments	1,018	1,020
Other long-term assets	274	278
Total assets	$ 68,880	$ 84,020
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 749	$ 1,834
Accrued liabilities	6,812	5,499
Contract research liability	678	1,946
Deferred revenue, current portion	5,768	5,728
Convertible subordinated notes		23,599
Other short-term liabilities	425	482
Total current liabilities	14,432	39,088
Deferred revenue, non-current portion	6,649	9,268
Other long-term liabilities	982	1,083
Commitments		
Stockholders equity:		
Common stock	8	7
Additional paid-in capital	316,345	287,689
Deferred royalties and commercial rights	(13,480)	(13,480)
Accumulated other comprehensive income	23	50
Accumulated deficit	(256,079)	(239,685)
Stockholders equity	46,817	34,581

Total liabilities and stockholders equity	$ 68,880	$ 84,020

The accompanying notes are an integral part of these condensed 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,	
	2008	2007	2008	2007
Collaborative research and development and other revenue	$ 3,867	$ 11,408	$ 8,136	$ 14,866
Product revenue, net	2,436	2,024	4,605	4,292
Total revenues	6,303	13,432	12,741	19,158
Operating expenses:				
Cost of revenues (1)	982	778	1,804	1,638
Research and development (1)	9,898	9,630	19,532	19,982
Selling, general and administrative (1)	4,074	3,683	7,953	7,221
Amortization of intangible assets	12	8	23	15
Total operating expenses	14,966	14,099	29,312	28,856
Loss from operations	(8,663)	(667)	(16,571)	(9,698)
Other income (expense):				
Interest and other income	368	908	936	1,886
Interest and other expense	(304)	(720)	(759)	(1,434)
Net other income	64	188	177	452
Net loss	$ (8,599)	$ (479)	$ (16,394)	$ (9,246)
Net loss per share, basic and diluted	$ (0.11)	$ (0.01)	$ (0.22)	$ (0.13)
Shares used in computing basic and diluted net loss per share	75,430	69,364	74,772	69,298

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

Cost of revenues	$ 31	$ 33	$ 66	$ 67
Research and development	1,360	1,097	2,967	2,253
Selling, general and administrative	674	555	1,449	1,223
Total stock-based compensation	$ 2,065	$ 1,685	$ 4,482	$ 3,543

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

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DURECT CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six months ended June 30,	
	2008	**2007**
Cash flows from operating activities		
Net loss	$ (16,394)	$ (9,246)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,342	1,152
Stock-based compensation	4,482	3,543
Changes in assets and liabilities:		
Accounts receivable	542	(9,506)
Inventories	(675)	13
Prepaid expenses and other assets	185	(81)
Accounts payable	(1,085)	259
Accrued and other liabilities	1,235	1,023
Contract research liability	(1,268)	544
Interest payable on convertible notes	(62)	
Deferred revenue	(2,579)	(2,644)
Total adjustments	2,117	(5,697)
Net cash used in operating activities	(14,277)	(14,943)
Cash flows from investing activities		
Purchases of property and equipment	(649)	(1,455)
Purchase of intangible assets	(25)	
Purchases of available-for-sale securities	(10,234)	(11,756)
Proceeds from maturities of available-for-sale securities	18,498	18,249
Net cash provided by investing activities	7,590	5,038
Cash flows from financing activities		
Payments on equipment financing obligations	(19)	(17)
Net proceeds from issuances of common stock	562	599
Net cash provided by financing activities	543	582
Net decrease in cash and cash equivalents	(6,144)	(9,323)
Cash and cash equivalents, beginning of the period	37,589	41,554
Cash and cash equivalents, end of the period	$ 31,445	$ 32,231

The accompanying notes are an integral part of these condensed 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 pharmaceutical and biotechnology company 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.

Basis of Presentation

The accompanying unaudited condensed 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 condensed 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, 2008, the operating results for the three and six months ended June 30, 2008 and 2007, and cash flows for the six months ended June 30, 2008 and 2007. The balance sheet as of December 31, 2007 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 condensed 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.

Reclassifications

Certain prior period amounts related to milestone revenue in the statements of operations have been reclassified to collaborative research and development and other revenues. Such reclassification did not impact the Company s net loss or financial position.

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 2008 (unaudited)	December 31, 2007
Raw materials	$ 560	$ 157
Work in process	1,012	666
Finished goods	1,081	1,140
Total inventories	$ 2,653	$ 1,963

During the first six months of 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 quarter of 2008 the Company made its first shipment of these materials to meet the production requirements of King Pharmaceuticals, which has rights to commercialize Remoxy upon approval by

the FDA. The Company included approximately $737,000 of these materials as inventory in its balance sheet as of June 30, 2008.

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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.

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.

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,	
	2008	2007	2008	2007
Collaborator				
Pain Therapeutics, Inc.	$ 1,861	$ 423	$ 4,009	$ 1,776
Endo Pharmaceuticals, Inc. (1)	836	1,302	1,634	2,499
Nycomed Danmark, APS (2)	763	8,763	1,525	9,525
Others	407	920	968	1,066
Total collaborative research and development revenue	$ 3,867	$ 11,408	$ 8,136	$ 14,866

Notes:

(1) Amounts shown include amortization of up-front fees equal to $547,000 for each of the three months ended June 30, 2008 and 2007, and $1.1 million for each of the six months ended June 30, 2008 and 2007, respectively.

(2) Amounts shown represent the amortization of up-front fees equal to $763,000 for each of the three months ended June 30, 2008 and 2007, and $1.5 million for each of the six months ended June 30, 2008 and 2007, respectively. Research and development expenses incurred by the Company in conjunction with the Nycomed collaboration and reimbursable by Nycomed are recorded as a reduction to total research and development expense. The 2007 figures include $8.0 million of milestone revenue recognized in connection with the Nycomed collaboration.

The Company amortizes up-front 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.

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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.

Research and Development Expenses

Research and development expenses are primarily comprised of salaries and benefits 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,	
	2008	2007	2008	2007
POSIDUR (1)	$ 2,491	$ 3,762	$ 4,346	$ 6,757
ELADUR	2,324	1,240	4,386	2,651
Remoxy and other ORADUR-based opioid drug candidates licensed to Pain Therapeutics	1,618	380	3,489	1,504
Biologics Programs	1,396	658	2,308	1,225
TRANSDUR-Sufentanil	314	877	636	1,533
CHRONOGESIC	22	583	83	1,344
Memryte (2)		30		1,184
Others	1,733	2,100	4,284	3,784
Total research and development expenses (3)	$ 9,898	$ 9,630	$ 19,532	$ 19,982

(1) In the three and six months ended June 30, 2008, research and development expenses for POSIDUR incurred by us but reimbursable by Nycomed under the terms of our agreement with Nycomed were $904,000 and $1.7 million, respectively, compared to $2.0 million and $4.1 million for the same periods in 2007, which are accounted for as a reduction of research and development expenses. In the three and six months ended June 30, 2008, research and development expenses for POSIDUR incurred by Nycomed but reimbursable by us under the terms of our agreement with Nycomed were $784,000 and $1.1 million, respectively, compared to $700,000 and $850,000 for the same periods in 2007, which are accounted for as additional research and development expenses.

(2) The reported research and development expense in the six months ended June 30, 2007 includes a one-time cash payment of $1.0 million which the Company made in January 2007 as part of the amendment of its license agreement with Voyager.

(3) Includes stock-based compensation expenses of $1.4 million and $3.0 million for three and six months ended June 30, 2008, compared to $1.1 million and $2.3 million for the same periods in 2007, respectively.

Comprehensive Loss

Components of other comprehensive income (loss), including unrealized gains and losses on the Company s available-for-sale securities, are included in total comprehensive loss. The difference between net loss and comprehensive loss in all periods presented resulted from unrealized gains and losses on available-for-sale investments.

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Net loss	$ (8,599)	$ (479)	$ (16,394)	$ (9,246)
Net change in unrealized gain on available-for-sale investments	(84)	(15)	(27)	13
Comprehensive loss	$ (8,683)	$ (494)	$ (16,421)	$ (9,233)

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Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period. 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 period, if dilutive, using the treasury stock method for options and warrants and the if-converted method for convertible subordinated notes. There is no difference between basic and diluted net loss per share as the Company incurred a net loss in each period presented and inclusion of common stock equivalents would have been antidilutive.

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Outstanding dilutive securities not included in diluted net loss per share				
Options to purchase common stock	15,693	11,911	15,932	12,061
Convertible notes (1)	6,281	11,853	6,887	11,853
Warrants	1	1	1	1
Total	21,975	23,765	22,820	23,915

(1) The convertible noteholders exchanged the remaining $23.6 million in aggregate principal amount of convertible notes into 7,491,745 shares of common stock in June 2008.

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 condensed balance sheets and amortizes the deferred rent over the terms of the lease to rent expense on the condensed statements of operations.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). In February 2008, the FASB issued FASB Staff Position No. FAS 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 those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, the Company has adopted the provisions of SFAS 157 with respect to its financial assets and liabilities only. SFAS 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 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 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. The adoption of SFAS 157 did not have a material impact on its financial statements.

In February 2007, FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB No. 115* (SFAS 159). The Statement permits entities to choose, at specified election dates, to measure many financial instruments and certain other items at fair value that are not currently measured at fair value. Unrealized gains and losses on items for which the fair value option has been elected would be reported in earnings at each subsequent reporting date. SFAS 159 also establishes presentation and disclosure requirements in order to facilitate comparisons between entities choosing different measurement attributes for similar types of assets and

liabilities. SFAS 159 does not affect existing accounting requirements for certain assets and liabilities to be carried at fair value. This statement is effective for fiscal years beginning after November 15, 2007 and is required to be adopted by the Company for the fiscal year ending December 31, 2008. The Company does not believe that the adoption of SFAS 159 will have a material impact on its financial statements.

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In June 2007, the Emerging Issues Task Force of the FASB reached a consensus on Issue No. 07-3 (EITF 07-3), *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. Under EITF 07-3, nonrefundable advance payments for goods or services that will be used or rendered for research and development activities should be deferred and capitalized. Such payments should be recognized as an expense as the goods are delivered or the related services are performed, not when the advance payment is made. If a company does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. The adoption of EITF 07-3 did not have a material impact on its financial statements.

In November 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 partners 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 will be required to apply the provisions through retrospective application to all collaborative arrangements existing at adoption as a change in accounting principle. The Company does not believe that the adoption of EITF 07-1 will have a material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations* (SFAS No. 141R). SFAS No. 141R amends SFAS 141 and provides revised guidance for recognizing and measuring identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree. It also provides disclosure requirements to enable users of the financial statements to evaluate the nature and financial effects of the business combination. It is effective for fiscal years beginning on or after December 15, 2008 and will be applied prospectively. The Company does not believe that the adoption of SFAS 141R will have a material impact on its financial statements.

Note 2. Strategic Agreements

Agreement with Nycomed

In November 2006, the Company entered into a collaboration agreement (the Agreement) with Nycomed Danmark, APS (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 select 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 the development of POSIDUR, the Company does not recognize revenue from the reimbursement of qualified research expenses by Nycomed. Rather, the Company records research expense equal to its share of the joint expenses incurred under the product development plan. The Company recorded a net reduction in research and development expenses of $120,000 and $590,000 for the three and six months ended June 30, 2008, compared to $1.3 million and $3.3 million for the same periods in 2007, respectively. This represents a net reimbursement from Nycomed in order that both parties bear 50% of the development expenses under the collaboration agreement for POSIDUR. The Company recognized $763,000 and $1.5 million for the three and six months ended June 30, 2008 and 2007, respectively, as collaborative research and development revenue from the amortization of the $14.0 million

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upfront fee received in 2006. In addition, the Company recognized an additional $8.0 million as collaborative research and development revenue, triggered by the achievement of a clinical development milestone under its Nycomed collaboration for the three and six months ended June 30, 2007, as compared to zero for the three and six months ended June 30, 2008.

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 and commercialize the Company s proprietary sufentanil transdermal patch development product (TRANSDUR-Sufentanil) in the U.S. and Canada. Under the terms of the agreement, Endo will assume all remaining development and regulatory filing responsibility in the U.S. and Canada, including the funding thereof. The Company will perform all formulation development for Endo unless the Company defaults on such obligations and the Company will be reimbursed for its fully allocated cost in performance of such work. Endo will also be responsible and pay for the manufacture, marketing, sales and distribution of TRANSDUR-Sufentanil in the U.S. and Canada.

Pursuant to the agreement, Endo was obligated to pay an upfront, nonrefundable fee of $10.0 million. In April 2005, Endo paid the Company the $10.0 million upfront fee. Endo is also obligated to pay to the Company additional payments of up to approximately $35.0 million in the aggregate if predetermined regulatory and commercial milestones are achieved. In addition, Endo reimburses the Company for all qualified research and development expenses incurred for TRANSDUR-Sufentanil. If commercialized, Endo will also pay the Company product royalties based on the net sales of TRANSDUR-Sufentanil under the agreement. The Company has the right to co-promote TRANSDUR-Sufentanil under terms specified in the agreement. The agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties and indemnities. 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, Endo shall have the right to terminate the agreement at any time without cause subject to a specified notice period and due to adverse product events, legal impediment or the issuance of a final, non-appealable court order enjoining Endo from selling TRANSDUR-Sufentanil in the U.S. and Canada as a result of an action for patent infringement by a third party, provided that in the latter instance, the Company will be required to pay Endo a termination fee ranging from $5.0 million to $10.0 million, depending on the date of termination.

The $10.0 million upfront fee is recognized as revenue ratably over the term of the Company s obliged continuing involvement with Endo with respect to TRANSDUR-Sufentanil. The term of the continuing involvement has been estimated based on the product development plan pursuant to the agreement. The Company recognized $547,000 as collaborative research and development revenue from the amortization of the $10.0 million upfront fee for each of the three months ended June 30, 2008 and 2007, and $1.1 million for each of the six months ended June 30, 2008 and 2007, respectively. Total collaborative research and development revenue recognized under this arrangement was $836,000 and $1.6 million for the three and six months ended June 30, 2008, compared with $1.3 million and $2.5 million for the same periods in 2007, respectively.

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. The Company will receive additional payments if certain development and regulatory milestones are achieved. 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 $1.9 million and $4.0 million for the three and six months ended June 30, 2008, compared with $423,000 and $1.8 million for the same periods in 2007, respectively.

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Agreement with Voyager Pharmaceutical Corporation

In July 2002, the Company entered into a development and commercialization agreement with Voyager Pharmaceutical Corporation, (Voyager). Under the terms of the agreement, the Company will collaborate with Voyager to develop a product using the DURIN technology to provide sustained release of leuprolide based on Voyager s patented method of treatment of Alzheimer s disease. The agreement also provides Voyager with the right to commercialize the product on a worldwide basis. The Company is responsible for preclinical development, product manufacture and other specified tasks. The Company will receive payments if certain development and regulatory milestones are achieved. If commercialized, the Company will receive royalties based on product sales. This agreement can be terminated by either party for material breach by the other party. Under the agreement, Voyager reimbursed the Company for qualified expenses incurred by the Company in connection with the development program for Memryte. The Company recognized collaborative research and development revenue related to research and development activities for Memryte based on reimbursement of qualified expenses as defined in the agreement, until August 2006 when the Company determined that the collectability of amounts owed was not reasonably assured.

Effective January 2007, the Company entered into an amendment to the agreement with Voyager. Under the amendment, among other changes to the Agreement, the royalty rate that the Company will receive on net sales of Memryte, if commercialized, was doubled (to 10-14% of net sales after the amendment), and in addition, the Company will now receive 10% of any upfront, milestone and other fees received by Voyager in the event that the product rights are sublicensed to a third party. As a part of the amendment, during the six months ended June 30, 2007, the Company paid Voyager $1.0 million in cash and forgave approximately $725,000 which was owed to us for previously provided services. No collaborative research and development revenue was recognized under the agreement with Voyager during either 2008 or 2007.

Agreement with EpiCept Corporation

On December 20, 2006, the Company entered into a license agreement with EpiCept Corporation (EpiCept) that will provide 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, will 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. This agreement can be terminated by either party for material breach by the other party and by the Company without cause. No amount was recorded under this agreement in both 2008 and 2007.

Agreement with ALZA Corporation

In April 1998, the Company entered into a development and commercialization agreement with ALZA Corporation (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 ALZA an additional 1,000,000 shares of the Company s common stock in connection with an amendment of the Agreement in April 2000. This agreement can be terminated by either party for material breach by the other party and by the Company without cause.

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Note 3. Goodwill and Intangible Assets

Intangible assets consist of the following (in thousands):

	June 30, 2008		
	Gross Intangibles	Accumulated Amortization	Net Intangibles
Developed technology	$ 3,600	$ (3,552)	$ 48
Patents	591	(457)	134
Other intangibles	3,260	(3,260)	
Total	$ 7,451	$ (7,269)	$ 182

	December 31, 2007		
	Gross Intangibles	Accumulated Amortization	Net Intangibles
Developed technology	$ 3,600	$ (3,540)	$ 60
Patents	566	(446)	120
Other intangibles	3,260	(3,260)	
Total	$ 7,426	$ (7,246)	$ 180

The net amount of intangible assets at June 30, 2008 was $182,000, which will be amortized as follows: $24,000 in the six months ending December 31, 2008, $48,700 in 2009, $37,000 in 2010, $17,800 in each of the years from 2011 to 2014, and $900 in 2015. Should any intangible assets become impaired, the Company will write them down to their estimated fair value.

Goodwill totaled $6.4 million at June 30, 2008 and December 31, 2007. In the fourth quarter of 2007, goodwill was evaluated and no indicators of impairment were noted. Should goodwill become impaired, we may be required to record an impairment charge to write the goodwill down to its estimated fair value.

Note 4. Fair Value Measurements

As of January 1, 2008, we adopted FASB Statement No. 157, *Fair Value Measurements* (SFAS 157). In February 2008, the FASB issued FASB Staff Position No. FAS 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 those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, we have adopted the provisions of SFAS 157 with respect to its financial assets and liabilities only. SFAS 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 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 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 adoption of SFAS 157 did not have a material effect on our financial position and results of operations, but SFAS 157 introduced new disclosures about how we value certain assets and liabilities. Much of the disclosure is focused on the inputs used to measure fair value, particularly in instances where the measurement uses significant unobservable (Level 3) inputs. Our 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 our financial assets that were measured on a recurring basis as of June 30, 2008 (in thousands):

	Level 1	Level 2	Level 3	Total
Money Market Funds	$	$ 113	$	$ 113
Certificates of Deposit		394		394
Commercial Paper		2,624		2,624
Corporate Debts		9,613		9,613
U.S. Government Agencies		30,586		30,586
Total	$	$ 43,330	$	$ 43,330

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

Note 5. Convertible Subordinated Notes Due June 2008

In June 2008, the holders of the Company s remaining $23.6 million in aggregate principal amount of convertible subordinated notes converted all remaining notes into 7,491,745 shares of our common stock at a conversion rate of 317.4603 shares per $1,000 principal amount of notes as set forth in the original indenture.

Note 6. Stock-Based Compensation

As of June 30, 2008, the Company has five stock-based employee compensation plans, which have not changed in 2007 or 2008. The employee stock-based compensation cost that has been included in the statements of operations was $2.1 million and $4.5 million for the three and six months ended June 30, 2008, compared to $1.7 million and $3.5 million for the same periods in 2007, respectively.

The following table summarizes the stock-based compensation expense for stock options and the Company s employee stock purchase plan that the Company recorded in the condensed statements of operations in accordance with SFAS 123(R) for the three and six months ended June 30, 2008 and 2007, respectively (in thousands).

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Cost of revenues	$ 31	$ 33	$ 66	$ 67
Research and development	1,360	1,097	2,967	2,253
Selling, general and administrative	674	555	1,449	1,223
Total stock-based compensation per FAS 123(R)	$ 2,065	$ 1,685	$ 4,482	$ 3,543

As of June 30, 2008 and 2007, $99,000 and $41,000, respectively, of stock-based compensation cost was capitalized in inventory on the Company s balance sheets.

We use the Black-Scholes option pricing model to value our stock options. The expected life computation is based on historical exercise patterns and post-vesting termination behavior. We considered our historical volatility in developing our 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, 2008 and 2007:

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Stock options				
Risk-free rate	3.19-3.55%	4.51-5.03%	2.67-3.55%	4.51-5.16%
Expected dividend yield				
Expected term (in years)	6	6.25	6	6.25
Volatility	82-83%	54-86%	81-83%	54-89%
Forfeiture	12.9%	14.7%	12.9%	14.7%

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	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Employee Stock Purchase Plan				
Risk-free rate	1.73-3.95%	4.63-5.01%	1.73-3.95%	4.63-5.01%
Expected dividend yield				
Expected term (in years)	1.25	1.25	1.25	1.25
Volatility	51-61%	50-59%	51-61%	50-59%

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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, 2008 and 2007 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 in this Form 10-Q may be identified by words such as believe, anticipate, intend, plan, estimate, expect, and s expressions and include, without limitation:

- Statements about the intended uses and therapeutic benefits of POSIDUR, Remoxy and other ORADUR-based opioid drug candidates, TRANSDUR-Sufentanil, ELADUR, Memryte and CHRONOGESIC;
- Statements about the timing, status and completion of current and anticipated clinical trials and regulatory milestones;
- Statements about potential payments to us under agreements with Nycomed, Endo, Pain Therapeutics, and Voyager; and
- Statements about anticipated future financial performance, including revenues, costs, and cash balances.

For a more detailed discussion of such forward-looking statements and the potential risks and uncertainties that may impact upon their accuracy, see the Overview sections of this Management s Discussion and Analysis of Financial Condition and Results of Operations and the Risk Factors included elsewhere in this Form 10-Q. These forward-looking statements reflect our view only as of the date of this report. Except as required by law, 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. [1]

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 intend to commercialize pharmaceutical systems that will deliver the right drug to the right place in the right amount at the right time to treat chronic or episodic diseases and conditions. By integrating chemistry and engineering advancements, we seek to achieve what drugs or devices alone cannot. Our pharmaceutical systems enable optimized therapy for a given disease or patient population by controlling the rate and duration of drug administration and providing sustained drug delivery.

In addition to developing our own proprietary products, we enter into strategic collaborations with pharmaceutical companies to develop and commercialize proprietary and enhanced pharmaceutical products based on our technologies. We have five disclosed on-going product candidates in development of which four are in collaboration with third-party pharmaceutical companies. 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 our 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.

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

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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 select other countries. Nycomed paid us an upfront license fee of $14.0 million in 2006 and an $8.0 million milestone payment in 2007, triggered by the achievement of a clinical development milestone, 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.

Phase IIb Inguinal Hernia Trial

Design

The POSIDUR Phase IIb clinical trial was designed to evaluate the tolerability, activity, dose response and pharmacokinetics of POSIDUR in patients undergoing open inguinal hernia repair. The study was conducted in Australia and New Zealand as a multi-center, randomized, double blind, placebo-controlled study in 122 patients. Study patients were randomized into three treatment groups: patients that were treated with POSIDUR 2.5 mL (n=43), POSIDUR 5 mL (n=47) and placebo (n=32). The co-primary efficacy endpoints for the study were Mean Pain Intensity on Movement area under the curve (AUC), a measure of pain over a period of 1-72 hours post-surgery, and the proportion of patients requiring supplemental opioid analgesic medication during the study. Secondary efficacy endpoints included Mean Pain Intensity on Movement AUC over the period 1-48 hours post-surgery, mean total consumption of supplemental opioid analgesic medication, and time to first use of supplemental opioid analgesic medication. The threshold for statistical significance was considered to be at the $p<0.05$ level.

Results

Pain Control

In relation to the co-primary endpoint of pain reduction as measured by Mean Pain Intensity on Movement AUC 1-72 hours post-surgery, the patient group treated with POSIDUR 5 mL reported thirty-one percent (31%) less pain versus placebo (p=0.0033). A secondary endpoint measure reported a thirty-five percent (35%) reduction of pain as measured by Mean Pain Intensity on Movement AUC for the period 1-48 hours post-surgery between the POSIDUR 5 mL treatment group versus placebo (p=0.0007).

Consumption of Supplemental Opioid Analgesic Medication

Fifty-three percent (53%) of the study patients in the POSIDUR 5 mL group took supplemental opioid analgesic medications versus seventy-two percent (72%) of the placebo patients (p=0.0909). Although this positive trend for this co-primary endpoint in favor of the POSIDUR 5 mL group was not statistically significant, both secondary endpoints measuring opioid analgesic medication consumption were met at a statistically significant level. During the periods of 1-24 hours, 24-48 hours and 48-72 hours after surgery, placebo patients consumed approximately 3.5 (p=0.0009), 2.9 (p=0.0190) and 3.6 (p=0.0172) times more supplemental opioid analgesic medications (mean total daily consumption of opioid analgesic medication in morphine equivalents), respectively, than the POSIDUR 5 mL treatment group. In addition, the median time to first use of supplemental opioid analgesic medication after surgery for the placebo patients was 2.7 hours versus >72 hours for the POSIDUR 5 mL treatment group (p=0.0197).

Dose Finding

POSIDUR administered at the dose of 5 mL showed statistically significant activity relative to placebo whereas POSIDUR administered at 2.5 mL showed a positive trend relative to placebo on certain parameters but the results were not statistically significant.

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Safety

The patient groups treated with POSIDUR 5 mL and POSIDUR 2.5 mL showed comparable safety profiles as the patient groups treated with placebo, and the drug administration appeared well tolerated. The side effects commonly observed with opioid medication use were less frequent in the POSIDUR 5 mL and 2.5 mL treatment groups compared to placebo.

Other Exploratory Phase II studies

In addition to the Phase IIb study described above, we have also been conducting smaller exploratory Phase II studies in hernia, shoulder arthroscopy and appendectomy surgeries to evaluate different application techniques, clinical design and conduct as well as other investigational factors. These trials have been conducted in multiple cohorts, generally consisting of approximately 6 to 21 patients in each treatment group. In all the exploratory studies, patient groups treated with POSIDUR 5 mL and POSIDUR 2.5 mL showed comparable safety profiles as the patient groups treated with placebo, and the drug administration appeared well tolerated. Some treatment groups from the hernia and shoulder exploratory studies utilizing POSIDUR have shown positive activity as measured by reduction of pain or consumption of supplemental opioid analgesic medication versus placebo, while other treatment groups have not. We are continuing to evaluate these studies to understand the different results observed, and intend to apply our learnings in the design of our Phase III program.

We have held an end-of-Phase II meeting with the FDA and are in dialogue with the FDA regarding the Phase III program for POSIDUR.

Remoxy and other ORADUR-based opioid drug candidates 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 December 2007, Pain Therapeutics and King Pharmaceuticals announced that the pivotal Phase III trial for Remoxy successfully met its primary endpoint ($p<0.01$) that was prospectively defined by the U.S. Food and Drug Administration s (FDA) during the Special Protocol Assessment process. In addition, the study achieved statistically significant results in secondary endpoints such as Quality of Analgesia ($p<0.01$) and Global Assessment ($p<0.01$). Pain Therapeutics has stated that they submitted the NDA for Remoxy with the FDA in June 2008 and pursuant to Prescription Drug User Fee Act (PDUFA) guidelines, the FDA is expected to determine whether to accept the NDA for filing within 90 days of submission. At that time Pain Therapeutics (the NDA sponsor) will also learn if the NDA filing was granted priority review. A priority review designation is given to drugs that offer real advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the time it takes FDA to review a NDA is reduced from 12 months to approximately 6 months.

During the first six months of 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 quarter of 2008 we made our first shipment of these materials to meet the production requirements of King Pharmaceuticals, which has rights to commercialize Remoxy upon approval by the FDA.

We have also worked with King and Pain Therapeutics on the development of ORADUR-based abuse-resistant opioid drug candidates in addition to Remoxy. In November 2006, Pain Therapeutics announced positive results from the Phase I clinical trial of an ORADUR-based opioid drug candidate. In addition, Pain Therapeutics has stated that it expects to file an Investigational New Drug application (IND) for a new ORADUR-based abuse-resistant opioid in 2008.

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 three days of relief provided with currently available opiate patches. We anticipate that the small size of our sufentanil patch (potentially as small as $1/5^{th}$ the size of currently marketed transdermal fentanyl patches for a therapeutically equivalent dose) may offer improved convenience and compliance for patients. In 2005, we successfully completed a Phase II clinical trial of TRANSDUR-Sufentanil in chronic pain. In March 2005, we entered into an agreement with Endo Pharmaceuticals (Endo) granting Endo exclusive rights to develop, market and commercialize TRANSDUR-Sufentanil in the U.S. and Canada. Endo has entered into an agreement with a contract manufacturer, 3M Company (3M), related to manufacturing process development and scale-up for TRANSDUR-Sufentanil. Endo commenced its Phase II program designed to evaluate the conversion of chronic pain patients treated with oral opioid products to TRANSDUR-Sufentanil in the second quarter of 2007. Endo has

stated that they expect to have data from a Phase II study by the end of 2008 and expect to hold an end-of-Phase II meeting with the FDA in late 2008 or early 2009.

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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 the second quarter of 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. The FDA recently granted to DURECT 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.

Other Programs

Memryte

In July 2002, we entered into a development and commercialization agreement, amended in January 2007 with Voyager under which we granted Voyager the exclusive, worldwide rights to develop and commercialize a product, Memryte, using the DURIN implant system to deliver the peptide leuprolide acetate to treat Alzheimer s disease based on Voyager s patented method of treatment.

In October 2005, Voyager initiated a Phase III clinical trial for Memryte, but the Phase III trial was truncated by Voyager in order to get an early look at potential efficacy. In the second quarter of 2007, Voyager informed its shareholders that it has observed positive outcome trends among women, but no positive effect among men in Voyager s truncated Phase III clinical trial for Memryte. Based on these results, Voyager has stated that it intends to focus its efforts on developing Memryte for the treatment of Alzheimer s disease in women and on seeking a potential collaborative partner for the program. There can be no assurance that Voyager or any other party will continue development of Memryte.

CHRONOGESIC® (sufentanil) Pain Therapy System

The CHRONOGESIC (sufentanil) Pain Therapy System is an osmotic implant that is intended to continuously deliver sufentanil for an extended duration. CHRONOGESIC is intended to treat chronic pain, and is based on the DUROS® System, a miniature osmotic pump capable of continuously delivering drugs for up to a year in duration. We granted to Endo exclusive commercialization rights for CHRONOGESIC in the U.S. and Canada pursuant to a Development, Commercialization and Supply License Agreement dated November 2002, which was terminated by Endo effective April 17, 2008, thus returning the rights to the product candidate back to us.

Biologics Programs

The proteins and genes identified by the biotechnology industry are large, complex, intricate molecules, and many are difficult to use 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.

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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 two and one-half years, we generated the majority of all collaborative research and development revenues from three collaborative agreements related to TRANSDUR-Sufentanil, Remoxy and other specified ORADUR-based oral opioids, and POSIDUR. Since the signing of the Nycomed agreement related to POSIDUR in November 2006, we have recognized collaborative research and development revenue from the amortization of the upfront payment of $14.0 million and milestone payment of $8.0 million received from Nycomed. However, in contrast to our other collaborations, due to the terms and nature of this collaboration, we do not recognize revenue from the reimbursement of qualified research expenses by Nycomed. 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.

Since our inception in 1998, we have had a history of operating losses. At June 30, 2008, we had an accumulated deficit of $256.1 million. Our net loss for the three and six months ended June 30, 2008 was $8.6 million and $16.4 million, respectively. Our losses were $24.3 million, $33.3 million and $18.1 million for the years ended December 31, 2007, 2006 and 2005, 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. We expect selling, general and administrative expenses to increase in the near future due to expected increases in patent and employee related costs to support our business activities. 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 collectability 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.

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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 our continuing involvement with the third party collaborator pursuant to the applicable agreement. Such period generally represents the research and development period set forth in the work plan defined in the respective agreements between us and our third-party collaborators.

Research and development revenue related to services performed under the collaborative arrangements with our corporate collaborators is recognized as the related research and development services are performed and the collectability of the amounts owed is reasonably assured. These research payments received under each respective agreement are not refundable and are generally based on reimbursement of qualified expenses, as defined in the agreements. Research and development expenses under the collaborative research and development agreements generally approximate or exceed the revenue recognized under such agreements over the term of the respective agreements. Deferred revenue may result when we do not expend the required level of effort during a specific period in comparison to funds received under the respective agreement. Of note, in regard to our collaboration with Nycomed, in contrast to our other collaborations, because we and Nycomed jointly control and fund the development of POSIDUR, we do not recognize revenue from the reimbursement of qualified research expenses from Nycomed but instead those reimbursements receivable from Nycomed are 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.

Research and Development Expenses

Research and development expenses are primarily comprised of salaries and benefits 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 the Company are recorded as a reduction to research and development expenses. Research and development expenses incurred by Nycomed and reimbursable by the Company are recorded as an addition to the Company s research and development expenses.

Accrued Liabilities and Contract Research Liabilities

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

Stock-Based Compensation

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

Fair Value Measurements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). In February 2008, the FASB issued FASB Staff Position No. FAS 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 those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, we have adopted the provisions of SFAS 157 with respect to its financial assets and liabilities only. SFAS 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 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 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.

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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.

We do not believe that the adoption of SFAS 157 had a material impact on our financial statements.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). In February 2008, the FASB issued FASB Staff Position No. FAS 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 those that are recognized or disclosed in the financial statements at fair value at least annually. Therefore, we have adopted the provisions of SFAS 157 with respect to its financial assets and liabilities only. SFAS 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 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 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. The adoption of SFAS 157 did not have a material impact on our financial statements.

In February 2007, FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB No. 115* (SFAS 159). The Statement permits entities to choose, at specified election dates, to measure many financial instruments and certain other items at fair value that are not currently measured at fair value. Unrealized gains and losses on items for which the fair value option has been elected would be reported in earnings at each subsequent reporting date. SFAS 159 also establishes presentation and disclosure requirements in order to facilitate comparisons between entities choosing different measurement attributes for similar types of assets and liabilities. SFAS 159 does not affect existing accounting requirements for certain assets and liabilities to be carried at fair value. This statement is effective for fiscal years beginning after November 15, 2007 and is required to be adopted by the Company for the fiscal year ending December 31, 2008. We do not believe that the adoption of SFAS 159 will have a material impact on our financial statements.

In June 2007, the Emerging Issues Task Force of the FASB reached a consensus on Issue No. 07-3 (EITF 07-3), *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*. Under EITF 07-3, nonrefundable advance payments for goods or services that will be used or rendered for research and development activities should be deferred and capitalized. Such payments should be recognized as an expense as the goods are delivered or the related services are performed, not when the advance payment is made. If a company does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. The adoption of EITF 07-3 did not have a material impact on our financial statements.

In November 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 partners 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 will be required to apply the provisions through retrospective application to all collaborative arrangements existing at adoption as a change in accounting principle. We do not believe that the adoption of EITF 07-1 will have a material impact on its financial statements.

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In December 2007, the FASB issued SFAS No. 141R, *Business Combinations* (SFAS No. 141R). SFAS No. 141R amends SFAS 141 and provides revised guidance for recognizing and measuring identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree. It also provides disclosure requirements to enable users of the financial statements to evaluate the nature and financial effects of the business combination. It is effective for fiscal years beginning on or after December 15, 2008 and will be applied prospectively. We do not believe that the adoption of SFAS 141R will have a material impact on our financial statements.

Results of Operations

Three and six months ended June 30, 2008 and 2007

Revenues. Net revenues were $6.3 million and $12.7 million in the three and six months ended June 30, 2008, respectively, compared to $13.4 million and $19.2 million for the corresponding periods in 2007. We recognized $8.0 million of milestone revenue in the three and six months ended June 30, 2007 compared to zero in the corresponding periods in 2008. Excluding the milestone revenue, total revenue in the three and six months ended June 30, 2008 increased compared to the same periods in 2007 primarily due to higher collaborative research and development revenue recognized from our agreement with Pain Therapeutics and higher product revenue, partially offset by lower collaborative research and development revenue from Endo and from feasibility agreements with various third parties.

Collaborative research and development and other revenue

We recognize revenues from collaborative research and development activities and service contracts. We recorded $3.8 million and $8.1 million of collaborative research and development revenue for the three and six months ended June 30, 2008, respectively, compared to $11.4 million and $14.9 million for the corresponding periods in 2007. Collaborative research and development revenue primarily 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, amortization of upfront fees and milestone payments associated with the license agreements. The decrease in collaborative research and development revenue in the three and six months ended June 30, 2008, as compared to the same period in 2007, was primarily attributable to our recognition of $8.0 million of milestone revenue in connection with our agreement for POSIDUR (collaboration with Nycomed) for the three and six months ended June 30, 2007, as compared to zero for the three and six months ended June 30, 2008. Excluding the impact of that milestone revenue, collaborative research and development revenue increased in the three and six months ended June 30, 2008 due to higher revenue recognized in connection with our agreement for Remoxy and other ORADUR-based opioid drug candidates (collaboration with Pain Therapeutics), partially offset by lower collaborative research and development revenue recognized in connection with our agreement for TRANSDUR-Sufentanil (collaboration with Endo) and from feasibility agreements compared with the same periods in 2007.

We received a $10.0 million up-front fee in connection with the license agreement signed with Endo in March 2005 relating to TRANSDUR-Sufentanil. The $10.0 million up-front fee is recognized as revenue ratably over the term of our continuing involvement with Endo with respect to TRANSDUR-Sufentanil. For each of the three and six months ended June 30, 2008 and 2007, we recognized $547,000 and $1.1 million in collaborative research and development revenue related to this upfront fee. The term of the continuing involvement has been estimated based on the current product development plan pursuant to the agreement.

We also received a $14.0 million up-front 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. The amount recognized in the each of the three and six months ended June 30, 2008 and 2007 as collaborative research and development revenue from the amortization of the up-front fee was $763,000 and $1.5 million, respectively.

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,	
	2008	2007	2008	2007
Collaborator				
Pain Therapeutics	$ 1,861	$ 423	$ 4,009	$ 1,776

Endo (1)	836	1,302	1,634	2,499
Nycomed (2)	763	8,763	1,525	9,525
Others	407	920	968	1,066
Total collaborative research and development revenue	$ 3,867	$ 11,408	$ 8,136	$ 14,866

(1) Amounts shown include amortization of up-front fees equal to $547,000 for each of the three months ended June 30, 2008 and 2007, and $1.1 million for each of the six months ended June 30, 2008 and 2007, respectively.

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(2) Amounts shown represent the amortization of up-front fees equal to $763,000 for each of the three months ended June 30, 2008 and 2007, and $1.5 million for each of the six months ended June 30, 2008 and 2007, respectively. Research and development expenses incurred by the Company in conjunction with the Nycomed collaboration and reimbursable by Nycomed are recorded as a reduction to total research and development expense. The 2007 figure includes $8.0 million of milestone revenue recognized in connection with the Nycomed collaboration.

We amortize up-front 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.

Milestone payments under collaborative arrangements are recognized as revenue upon achievement of the 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 revenue is only recognized upon the achievement of a milestone event if we have no future performance obligations related to that milestone payment. We recorded $0 of milestone revenue for each of the three and six months ended June 30, 2008 compared with $8.0 million of milestone revenue from our Nycomed collaboration due to the achievement of a clinical development milestone for POSIDUR in the same periods in 2007.

We recognized $17,000 and $49,000 in revenue from service contracts in the three and six months ended June 30, 2008 compared to $0 in the same periods in 2007. Service contract revenues recognized in 2008 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 such polymer-related service contracts 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 $2.4 million and $4.6 million in the three and six months ended June 30, 2008, respectively, compared to $2.0 million and $4.3 million for the corresponding periods in 2007. The increase was primarily due to higher average selling prices from our ALZET product line and LACTEL polymer product line in the three and six months ended June 30, 2008, compared with the same periods in 2007.

Cost of revenues. Cost of revenues was $982,000 and $1.8 million for the three and six months ended June 30, 2008, respectively, compared to $778,000 and $1.6 million for the corresponding periods in 2007. The increase in the cost of product revenue in the three and six months ended June 30, 2008 was primarily the result of higher product revenue by our ALZET and LACTEL product lines in these periods. Cost of service revenue was $4,000 and $19,000 for the three and six months ended June 30, 2008, respectively, compared to $0 for the corresponding periods in 2007 due to an increase in our service contract revenue related to our polymer business in 2008. Stock based compensation expense recognized under SFAS 123(R) related to cost of revenues was $31,000 and $33,000 for the three months ended June 30, 2008 and 2007, and $66,000 and $67,000 for the six months ended June 30, 2008 and 2007, respectively.

As of June 30, 2008 and 2007, we had 32 and 22 manufacturing employees, respectively. The increase in 2008 was due to the shifting of research and development employees to manufacturing as we began commercial manufacturing of certain excipients that are components of Remoxy. We expect cost of revenue to increase in 2008 as we begin to generate product revenue from selling these excipients to King Pharmaceuticals.

Research and Development. Research and development expenses are primarily comprised of salaries and benefits associated with R&D personnel, overhead and facility costs, preclinical and non-clinical development costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. Research and development expenses were $9.9 million and $19.5 million for the three and six months ended June 30, 2008, respectively, compared to $9.6 million and $20.0 million for the corresponding periods in 2007. The increase in the three months ended June 30, 2008 was primarily attributable to higher development costs associated with Remoxy and other ORADUR-based opioid drug candidates licensed to Pain Therapeutics, ELADUR and our biologics programs, partially offset by decreased clinical trial expenses for POSIDUR, decreased development costs associated with CHRONOGESIC and TRANSDUR-Sufentanil and other research programs compared with the same period in 2007 as more fully discussed below. The decrease in the six months ended June 30, 2008 was primarily attributable to decreased clinical trial expenses for POSIDUR, decreased expense related to the development of Memryte (primarily $1.0 million paid in connection with our amended agreement with Voyager in the first quarter of 2007), decreased development costs associated with CHRONOGESIC and TRANSDUR-Sufentanil, partially offset by higher development costs associated with Remoxy and other

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ORADUR-based opioid drug candidates licensed to Pain Therapeutics, ELADUR, our biologics programs and other research programs compared with the same period in 2007 as more fully discussed below. Stock based compensation expense recognized under SFAS 123(R) related to research and development personnel was $1.4 million and $3.0 million for the three and six months ended June 30, 2008, respectively, and $1.1 million and $2.3 million for the three and six months ended June 30, 2007, respectively.

POSIDUR

Our research and development expenses for POSIDUR decreased to $2.5 million and $4.3 million in the three and six months ended June 30, 2008 from $3.8 million and $6.8 million in the same period in 2007. The decreases were primarily due to lower 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 $904,000 and $1.7 million in the three and six months ended June 30, 2008, respectively, compared to $2.0 million and $4.1 million for the corresponding periods in 2007, 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 $784,000 and $1.1 million in the three and six months ended June 30, 2008, respectively, compared to $700,000 and $850,000 for the corresponding periods in 2007, 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 reduced by $120,000 and $590,000 in the three and six months ended June 30, 2008, respectively, compared to $1.3 million and $3.3 million for the corresponding periods in 2007. The net reduction in research and development expenses represents a net reimbursement from 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 increased to $2.3 million and $4.4 million in the three and six months ended June 30, 2008 from $1.2 million and $2.7 million in the same periods in 2007. The increases were primarily due to higher employee costs and contract manufacturing expenses related to manufacturing scale-up and processing activities to secure additional Phase II and Phase III supplies for this product candidate in 2008.

Remoxy and other ORADUR-based opioid drug candidates

Our research and development expenses for Remoxy and other opioids partnered with Pain Therapeutics increased to $1.6 million and $3.5 million in the three and six months ended June 30, 2008 from $380,000 and $1.5 million in the same periods in 2007. The increases were primarily due to increased NDA support activities for Remoxy as well as additional formulation and clinical manufacturing activities for other ORADUR-based opioid drug candidates in 2008.

Biologics Programs

Our research and development expenses for biologics programs increased to $1.4 million and $2.3 million in the three and six months ended June 30, 2008, respectively, compared to $658,000 and $1.2 million for the corresponding periods in 2007. The increases were primarily due to higher external costs and employee related costs in support of these programs in 2008.

TRANSDUR-Sufentanil

Our research and development expenses for TRANSDUR-Sufentanil decreased to $314,000 and $636,000 in the three and six months ended June 30, 2008, respectively, compared to $877,000 and $1.5 million for the corresponding periods in 2007. The decreases were primarily due to lower technology transfer activities performed in support of this drug candidate in 2008.

CHRONOGESIC® (sufentanil) Pain Therapy System

Our research and development expenses for CHRONOGESIC decreased to $22,000 and $83,000 in the three and six months ended June 30, 2008, respectively, compared to $583,000 and $1.3 million for the corresponding periods in 2007. The decreases were primarily due to lower employee related costs and external development expenses for this drug candidate in 2008.

Memryte

Our research and development expenses for Memryte decreased to zero in both the three and six months ended June 30, 2008, respectively, compared to $30,000 and $1.2 million for the corresponding periods in 2007 as we did not engage in any development activities related to Voyager in the first six months of 2008. The reported research and development expense in the six months ended June 30, 2007 includes a one-time cash payment of $1.0 million which we made in January 2007 as part of the amendment of our license agreement with Voyager.

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Other DURECT Research Programs

Our research and development expenses for all other programs decreased to $1.7 million in the three months ended June 30, 2008 compared to $2.1 million for the corresponding period in 2007 primarily due to lower employee related costs for these programs in the second quarter of 2008. Our research and development expenses for all other programs increased to $4.3 million in the six months ended June 30, 2008 compared to $3.8 million for the corresponding period in 2007 primarily due to higher employee related costs and increased formulation and clinical development activities for these programs.

As of June 30, 2008, we had 109 research and development employees compared with 118 as of the corresponding date in 2007; this decrease largely reflects the shifting of employees from research and development to manufacturing as we began commercial manufacturing of certain excipients that are components of Remoxy in 2008. 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,	
	2008	2007	2008	2007
POSIDUR (1)	$ 2,491	$ 3,762	$ 4,346	$ 6,757
ELADUR	2,324	1,240	4,386	2,651
Remoxy and other ORADUR-based opioid drug candidates licensed to Pain Therapeutics	1,618	380	3,489	1,504
Biologics Programs	1,396	658	2,308	1,225
TRANSDUR-Sufentanil	314	877	636	1,533
CHRONOGESIC	22	583	83	1,344
Memryte (2)		30		1,184
Others	1,733	2,100	4,284	3,784
Total research and development expenses (3)	$ 9,898	$ 9,630	$ 19,532	$ 19,982

(1) In the three and six months ended June 30, 2008, research and development expenses for POSIDUR incurred by us but reimbursable by Nycomed under the terms of our agreement with Nycomed were $904,000 and $1.7 million, respectively, compared to $2.0 million and $4.1 million for the same periods in 2007, which were accounted for as a reduction of research and development expenses. In the three and six months ended June 30, 2008, research and development expenses for POSIDUR incurred by Nycomed but reimbursable by us under the terms of our agreement with Nycomed were $784,000 and $1.1 million, respectively, compared to $700,000 and $850,000 for the same periods in 2007, which were accounted for as additional research and development expenses.

(2) The reported research and development expense in the six months ended June 30, 2007 includes a one-time cash payment of $1.0 million which we made in January 2007 as part of the amendment of our license agreement with Voyager.

(3) Includes stock-based compensation expenses of $1.4 million and $3.0 million for three and six months ended June 30, 2008, compared to $1.1 million and $2.3 million for the same periods in 2007, respectively.

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 collaborative development programs with third-parties, 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.

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Selling, General and Administrative. Selling, general and administrative expenses are primarily comprised of salaries and benefits 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 $4.1 million and $8.0 million for the three and six months ended June 30, 2008, respectively, compared to $3.7 million and $7.2 million for the corresponding periods in 2007. The increase in the three and six months ended June 30, 2008 was primarily attributable to higher patent related costs as we continue to expand our patent portfolio and higher stock based compensation expense. Stock-based compensation expense recognized under SFAS 123(R) related to selling, general and administrative personnel was $674,000 and $1.4 million for the three and six months ended June 30, 2008, compared to $555,000 and $1.2 million for the three and six months ended June 30, 2007, respectively.

As of June 30, 2008, we had 38 selling, general and administrative personnel compared with 37 as of the corresponding date in 2007. We expect selling, general and administrative expenses to increase in the near future due to expected increases in patent related costs and in employee related costs to support our business activities.

Amortization of intangible assets. Amortization of intangible assets was $12,000 and $23,000 for the three and six months ended June 30, 2008, respectively, compared to $8,000 and $15,000 for the corresponding periods in 2007, respectively. The amortization of intangible assets increased in the three and six months ended June 30, 2008 as we acquired additional patents in the fourth quarter of 2007 and the first quarter of 2008. We continue to amortize the existing intangible assets at a constant rate over their estimated useful lives. In 2007, goodwill was evaluated for impairment in accordance with SFAS 142. Based on our evaluation, no indicators of impairment were noted. Should goodwill become impaired in the future, we may be required to record an impairment charge to write the goodwill down to its estimated fair value.

The net amount of intangible assets at June 30, 2008 was $182,000, which will be amortized as follows: $24,000 in the six months ending December 31, 2008, $48,700 in 2009, $37,000 in 2010, $17,800 in each of the years from 2011 to 2014, and $900 in 2015. Should any intangible assets become impaired, the Company will write them down to their estimated fair value.

Other Income (Expense). Interest and other income was $368,000 and $936,000 for the three and six months ended June 30, 2008, respectively, compared to $908,000 and $1.9 million for the corresponding periods in 2007, respectively. 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, 2008 compared with the same periods in 2007.

Interest and other expense was $304,000 and $759,000 for the three and six months ended June 30, 2008, respectively, compared to $720,000 and $1.4 million for the corresponding periods in 2007, respectively. The decrease in interest expense in the three and six months ended June 30, 2008 was primarily due to lower outstanding balances on our convertible notes in the three and six months ended June 30, 2008 compared with the same periods of 2007.

Liquidity and Capital Resources

We had cash, cash equivalents and investments totaling $47.6 million at June 30, 2008 compared to $62.0 million at December 31, 2007. These balances include $1.0 million of interest-bearing marketable securities classified as restricted investments on our balance sheets as of June 30, 2008 and December 31, 2007. The decrease in cash, cash equivalents and investments during the six months ended June 30, 2008 was primarily the result of ongoing operating expenses, partially offset by payments received from customers.

Working capital was $35.3 million and $25.7 million at June 30, 2008 and December 31, 2007, respectively. The increase was primarily attributable to the exchange of the $23.6 million in aggregate principal amount of convertible notes at maturity in June 2008 into approximately 7.5 million shares of common stock, partially offset by $14.3 million of cash used for operations during the six months ended June 30, 2008.

We used $14.3 million of cash for operations for the six months ended June 30, 2008 compared to $14.9 million for the corresponding period in 2007. 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 decreases in accounts receivable from our third party collaborators, contract research liability and accounts payable for the six months ended June 30, 2008, partially offset by an increase in net loss compared to the same period in 2007.

We received $7.6 million of cash from investing activities for the six months ended June 30, 2008 compared to $5.0 million for the corresponding period in 2007. The increase in cash provided by investing activities was primarily due to higher net proceeds received from the maturing of our investments and a decrease in purchases of short-term and long-term investments for the six months ended June 30, 2008 compared to the same period in 2007.

We received $543,000 of cash from financing activities for the six months ended June 30, 2008 compared to $582,000 for the corresponding period in 2007. The decrease was primarily due to lower proceeds from exercises of stock options in the six months ended June 30, 2008 compared to the same period in 2007.

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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 convertible at the option of the note holders into our common stock at a conversion rate of 317.4603 shares per $1,000 principal amount of notes, or $3.15 per share. Interest on the notes was payable semi-annually in arrears in June and December. From the third quarter of 2005 through October 2007, we exchanged an aggregate of approximately $36.4 million in principal amount of our 6.25% convertible subordinated notes in individually negotiated transactions with note holders, pursuant to which we issued approximately 11.6 million shares of our common stock, and made cash payments in the aggregate amount of approximately $3.8 million. In June 2008, the remaining $23.6 million in aggregate principal amount of convertible notes were converted into approximately 7.5 million shares of our common stock.

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 are due semi-annually and principal payments are due annually. Principal payments increase in annual increments from $150,000 to $240,000 over the term of the bonds until the principal is fully amortized 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, 2008, the remaining principal payments of the bonds were $465,000.

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.

During the six months ended June 30, 2008, 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, 2007 other than the elimination of $23.6 million convertible subordinated notes due to their exchange in June 2008 into common stock.

We anticipate incurring capital expenditures of approximately $2.0 million 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 significant 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 and the extent to which we earn milestone revenues, 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, will earn milestone revenues 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.

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

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.

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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, 2008, approximately 78% of our investment portfolio is composed of investments with original maturities of one year or less and approximately 63% of our investment portfolio matures less than 90 days from the date of purchase.

The following table presents the amounts of our cash equivalents and investments that may be subject to interest rate risk and the average interest rates as of June 30, 2008 by year of maturity (dollars in thousands):

	2008	2009	2010	Total
Cash equivalents:				
Fixed rate	$ 27,081	$	$	$ 27,081
Average fixed rate	2.18%			2.18%
Variable rate	$ 113	$	$	$ 113
Average variable rate	2.72%			2.72%
Short-term investments:				
Fixed rate	$ 5,702	$ 5,157	$	$ 10,859
Average fixed rate	4.48%	4.02%		4.25%
Long-term investments:				
Fixed rate	$	$ 2,866	$ 1,393	$ 4,259
Average fixed rate		3.71%	3.42%	3.61%
Restricted investments:				
Fixed rate	$ 1,018	$	$	$ 1,018
Average fixed rate	2.23%			2.23%
Total investment securities	$ 33,914	$ 8,023	$ 1,393	$ 43,330
Average rate	2.86%	3.91%	3.42%	3.06%

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.

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.

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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. Other than for Remoxy, we have not yet selected the drug dosages nor finalized the formulation or the system design of any of our pharmaceutical systems, including POSIDUR, TRANSDUR-Sufentanil, ELADUR, our ORADUR-based opioid drug candidates besides Remoxy, Memryte and CHRONOGESIC, 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 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 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, our ORADUR-based opioid drug candidates besides Remoxy, Memryte, CHRONOGESIC 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 with Remoxy under an approved Special Protocol Assessment (SPA) with the FDA; the NDA was submitted to the FDA in June 2008.

POSIDUR A Phase IIb clinical trial was completed and an end of Phase II meeting was held with the FDA. We are currently in dialogue with the FDA regarding our Phase III program.

TRANSDUR-Sufentanil Patch Endo, our collaborator for the U.S. and Canadian markets, commenced its Phase II clinical program for TRANSDUR-Sufentanil in June 2007. Endo has stated that they expect to have data from a Phase II study by the end of 2008 and expect to hold an end-of-Phase II meeting with the FDA in late 2008 or early 2009.

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ELADUR A Phase IIa clinical trial was completed and positive results were reported in the fourth quarter of 2007. We are conducting manufacturing scale-up and processing activities to secure additional Phase II and Phase III supplies.

Second ORADUR Opioid Drug Candidate under Pain Therapeutics/King alliance In November 2006, Pain Therapeutics announced positive results from a Phase I clinical trial.

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 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 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 that could delay commercialization of such pharmaceutical systems and harm our business and financial conditions.

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

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 trial protocols or on the required data we or they must collect to continue with our clinical trials or eventually commercialize our pharmaceutical systems.

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We or our third-party collaborators, as applicable, may also encounter delays or rejections due to regulatory actions, including those 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 are awaiting regulatory review or action with respect to several of our pharmaceutical systems. For Remoxy, we are awaiting notification from FDA as to whether the Remoxy NDA will be accepted, and if accepted, whether the NDA will be approved. With respect to POSIDUR, we have been in lengthy dialogue with FDA with respect to our Phase III program. There can be no assurance that FDA will provide us with the actions or approvals we desire or seek in a timely fashion, which could materially harm the prospects of our product candidates and our business. 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.

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, Memryte, CHRONOGESIC, and the ORADUR-based opioid drug candidates beyond Remoxy. If we and our third-party collaborators, where relevant, fail to timely complete the development of the manufacturing process for our pharmaceutical systems, we and our third-party collaborators, where relevant, will not be able to timely produce product for clinical trials and commercialization of our pharmaceutical systems. We have also committed to manufacture and supply pharmaceutical systems or components under a number of our collaborative agreements with third-party companies. We have limited experience manufacturing pharmaceutical products, and we may not be able to timely accomplish these tasks. If we and our third-party collaborators, where relevant, fail to develop manufacturing processes to permit us to manufacture a pharmaceutical system or component at an acceptable cost, then we and our third-party collaborators may not be able to commercialize that pharmaceutical system or we may be in breach of our supply obligations to our third-party collaborators.

Our manufacturing facility in Cupertino is a multi-disciplinary site that we have used to manufacture only research and clinical supplies of several of our pharmaceutical systems under good manufacturing practices (GMP), including POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy and other ORADUR-based opioid drug candidates, Memryte and CHRONOGESIC. 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.

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 financials results.

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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

identification of serious and unanticipated adverse side effects in our pharmaceutical systems under development.

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, 2008, had an accumulated deficit of approximately $256.1 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 marketing, 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.

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 expect to generate sufficient revenues from commercial products to cover expenses or achieve profitability in the near future.

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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;
- 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.

Our near-term revenues depend on collaboration agreements with other companies. These agreements subject us to obligations which must be fulfilled and require us to manage complex relationships with 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 and the attainment of milestones set forth in the agreements. We may not be able to fulfill our obligations or attain milestones set forth in any specific agreement, which could cause our revenues to fluctuate or be less than anticipated and may expose us to liability for contractual breach. In addition, these agreements may require us to devote significant time and resources to communicating with and managing our relationship 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 Endo with respect to TRANSDUR-Sufentanil, Pain Therapeutics with respect to Remoxy and other ORADUR-based products incorporating specified opioids, Nycomed with respect to POSIDUR, and Voyager with respect to Memryte, 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 will be reduced or not materialize, and our development products related to those agreements may not be commercialized.

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

Our future 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 Endo related to the development, promotion and distribution of TRANSDUR-Sufentanil in the United States and Canada once such product is approved for commercialization. In addition, we have entered into agreements with Pain Therapeutics, Nycomed and Voyager 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 and Memryte, 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, 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. 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, manufacture, marketing or sale of these pharmaceutical systems. If any of these events occur, we may not be able to develop our technologies or 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.

In the second quarter of 2007, Voyager informed its shareholders that it has observed positive outcome trends among women, but no positive effect among men in Voyager s truncated Phase III clinical trial for Memryte. Based on these results, Voyager has stated that it intends to focus its efforts on developing Memryte for the treatment of Alzheimer s disease in women and on seeking a potential collaborative partner for the program. If Voyager is unable to raise the required money to fund its continued operations or if Voyager is unable to enter into an arrangement with a collaborator, it will not be able to continue to develop or commercialize Memryte.

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

We may develop our own sales force to market POSIDUR and to co-promote, along with Endo, TRANSDUR-Sufentanil in the United States but we have limited sales experience and may not be able to do so effectively

We currently plan to develop our own sales force to market POSIDUR in the United States and to co-promote, along with Endo, TRANSDUR-Sufentanil in the United States, if such pharmaceutical systems are 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;

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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 other ORADUR-based opioid drug candidates, Memryte and CHRONOGESIC) 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 other ORADUR-based opioid drug candidates and certain other pharmaceuticals systems we have under development. The reliance on a sole or limited number of suppliers could result in:

delays associated with redesigning a pharmaceutical system due to a failure to obtain a single source component;

an inability to obtain an adequate supply of required components; and

reduced control over pricing, quality and delivery time.

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

If we are unable to adequately protect 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 patents, maintain trade secret protection and operate without infringing the proprietary rights of others. As of July 31, 2008, we held 53 issued U.S. patents and 283 issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have 98 pending U.S. patent applications and have filed 103 patent applications under the Patent Cooperation Treaty, from which 553 national phase applications are currently pending in Europe, Australia, Japan, Canada and other countries. Our patents expire at various dates starting in the year 2012. Our expenditures to prosecute and maintain our patents are significant, especially for a company of our size and development stage. If our patents do not provide valuable and enforceable rights to our business, we may not derive any benefit from these expenditures.

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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 including the Patent Reform Act of 2007 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.

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

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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.

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. TRANSDUR-Sufentanil patch, Remoxy, our other ORADUR-based opioid drug candidates, and CHRONOGESIC and other pharmaceutical systems we have under development contain opioids which are classified as Schedule II 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.

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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. 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 2007 and determined that goodwill was not impaired as of December 31, 2007. 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.

In December 2004, the FASB issued Statement No. 123 (revised 2004, or SFAS 123(R), *Share-Based Payment,* which was originally effective for annual or interim periods beginning after June 15, 2005. SFAS 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and will require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and stock issued under our employee stock purchase plans. We adopted SFAS 123(R) using the modified prospective basis on January 1, 2006. Our adoption of SFAS 123(R) has and will continue to have a material adverse impact on our condensed results of operations and will adversely impact or delay our profitability. Furthermore, we have issued to ALZA common stock and a warrant to purchase common stock with an aggregate value of approximately $13.5 million, which will be amortized over time based on future sales of our DUROS-based products and which could also adversely impact or delay our profitability.

Global credit and financial market conditions could negatively impact the value of our current portfolio of cash equivalents or short-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 remaining maturities of more than 90 days and less than one year at the time of purchase. 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 or short-term investments since June 30, 2008, 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 or short-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 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 growth

Our success will depend on the timely expansion of our operations and the effective management of growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage such growth, we must expand our facilities, augment our operational, financial and management systems and hire, train and supervise additional qualified personnel. If we were unable to manage growth 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, Memryte and CHRONOGESIC, 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, Alpharma, 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, QLT, Pacira Pharmaceuticals, EpiCept, Innocoll, Inovio, Nektar, Focal, I-Flow, Anesiva, NeurogesX, Alexza and others. Some of these competitors may be addressing the same therapeutic areas or indications as we are. Our current and potential competitors may succeed in obtaining patent protection or commercializing products before us. Many of these entities have significantly greater research and development capabilities than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors financial, marketing, manufacturing and other resources.

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

The widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our pharmaceutical systems even if commercialized. Chronic and post-operative pain are currently being treated by oral medication, transdermal drug delivery systems, such as drug

patches, and implantable drug delivery devices which will be competitive with our pharmaceutical systems. These treatments are widely accepted in the medical community and have a long history of use. The established use of these competitive products may limit the potential for our pharmaceutical systems to receive widespread acceptance if commercialized.

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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 opioids, Memryte and CHRONOGESIC. 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 payers such as insurance companies, health maintenance organizations, hospital formularies and other health plan administrators.

Physicians, patients, payers 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 payers, 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 payers 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 payers 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 payers

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.

Legislative actions, potential new accounting pronouncements and higher insurance costs 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

We have engaged primarily in research and development, licensing technology, raising capital and recruiting scientific and management personnel and, to a lesser extent, sales and marketing of products that we do not consider core to our business. We have no approved pharmaceutical system products. This history does not enable investors to fully assess our ability to successfully develop our pharmaceutical systems, achieve market acceptance of our pharmaceutical systems and respond to competition. Furthermore, we anticipate that our quarterly and annual results of operations will 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

In the past, we have issued and have assumed, pursuant to the SBS acquisition, options and warrants to acquire common stock. To the extent any outstanding options are ultimately exercised, there will be dilution to investors. In addition, the recent conversion of our 6.25% convertible subordinated notes resulted in our issuance of 7,491,745 shares of common stock. Investors may experience further dilution of their investment if we raise capital through the sale of additional equity securities or debt securities with an equity component or grant additional stock options to employees and consultants. Any sales in the public market of the common stock as a result of convertible securities or through exercises of employee stock options could adversely affect prevailing market prices for our common stock.

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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 Endo, Pain Therapeutics or its commercialization sublicense King Pharmaceuticals, Nycomed or Voyager) to develop and commercialize successfully the respective pharmaceutical systems they are developing;

adverse results (including adverse events) or delays in our clinical trials of POSIDUR, TRANSDUR-Sufentanil, ELADUR, Remoxy, our other ORADUR-based opioid drug candidates, Memryte, CHRONOGESIC or other pharmaceutical systems;

action by the FDA and other regulatory authorities, including failure to accept the NDA submission for Remoxy, , non-approval of our pharmaceutical systems, including failure to approve the NDA for Remoxy, or delays in the FDA or other foreign regulatory agency review process, including failure to provide us with timely feedback on our POSIDUR Phase III program or the requirement of additional studies or development activities that would delay our programs;

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, including halting of clinical trials or development or marketing activities;

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 investors 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.

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

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

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

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

the election of directors;

the amendment of charter documents;

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

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

our certificate of incorporation, our bylaws, Delaware law and our stockholder rights plan contain provisions that could discourage another company from acquiring us;

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

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

providing for a dividend on our common stock, commonly referred to as a poison pill , which can be triggered after a person or group acquires 17.5% or more of common stock;

providing for a classified board of directors with staggered terms;

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

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

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 25, 2008, the Annual Meeting of Stockholders of DURECT Corporation was held at our offices in Cupertino, California.

An election of Class II 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, 2011:

David R. Hoffmann	(60,785,743 votes for, 4,428,455 votes withheld)
Jon S. Saxe	(60,056,994 votes for, 5,157,204 votes withheld)

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

James E. Brown
Simon X. Benito
Terrence F. Blaschke
Michael D. Casey
Armand P. Neukemans
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, 2008 (65,002,826 votes in favor, 154,007 votes opposed, 57,365 votes abstaining and 0 non-votes).

ITEM 5. ***Other Information***

None

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ITEM 6. Exhibits

(a) Exhibits:

10.50	Lease between the Company and KLP Properties dated as of April 23, 2008.
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 8, 2008

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

Date: August 8, 2008