DURECT CORP
Form 10-Q
November 08, 2007
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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 September 30, 2007

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 or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer x 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 October 31, 2007, there were 74,056,896 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, except per share amounts)

	September 30, 2007 (unaudited)	December 31, 2006 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,030	$ 41,554
Short-term investments	27,314	28,297
Accounts receivable, net of allowances of $52 and $1, respectively	5,437	2,152
Inventories	2,027	2,052
Prepaid expenses and other current assets	1,989	1,744
Total current assets	72,797	75,799
Property and equipment, net	7,918	7,451
Goodwill	6,399	6,399
Intangible assets, net	88	111
Long-term investments	1,983	10,472
Restricted investments	1,283	1,284
Other long-term assets	280	969
Total assets	$ 90,748	$ 102,485
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 606	$ 864
Accrued liabilities	7,051	4,522
Contract research liability	1,536	1,624
Interest payable on convertible notes	604	97
Deferred revenue, current portion	5,239	5,348
Equipment financing obligations, current portion	37	34
Bonds payable, current portion	210	210
Convertible subordinated notes	33,145	
Other short-term liabilities	149	
Total current liabilities	48,577	12,699
Equipment financing obligations, noncurrent portion	113	141
Bonds payable, noncurrent portion	465	465
Convertible subordinated notes		37,337
Deferred revenue, noncurrent portion	10,578	14,507
Other long-term liabilities	780	304
Commitments		
Stockholders equity:		
	7	7

Common stock, $0.0001 par value: 110,000 shares authorized; 70,929 and 69,212 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively		
Additional paid-in capital	276,171	265,896
Deferred royalties and commercial rights	(13,480)	(13,480)
Accumulated other comprehensive loss	11	(45)
Accumulated deficit	(232,474)	(215,346)
Stockholders equity	30,235	37,032
Total liabilities and stockholders equity	$ 90,748	$ 102,485

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 September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Collaborative research and development revenue	$ 2,992	$ 3,158	$ 9,858	$ 10,264
Milestone revenue			8,000	
Product revenue, net	1,940	1,976	6,232	6,189
Total revenues	4,932	5,134	24,090	16,453
Operating expenses:				
Cost of revenues (1)	780	666	2,418	2,265
Research and development (1)	8,858	9,930	28,840	25,643
Selling, general and administrative (1)	3,135	3,346	10,356	9,540
Amortization of intangible assets	8	22	23	416
Total operating expenses	12,781	13,964	41,637	37,864
Loss from operations	(7,849)	(8,830)	(17,547)	(21,411)
Other income (expense):				
Interest and other income	906	957	2,792	2,841
Interest expense	(716)	(710)	(2,150)	(2,719)
Debt conversion expense	(223)		(223)	(2,287)
Net other income (expense)	(33)	247	419	(2,165)
Net loss	$ (7,882)	$ (8,583)	$ (17,128)	$ (23,576)
Net loss per share, basic and diluted	$ (0.11)	$ (0.12)	$ (0.25)	$ (0.36)
Shares used in computing basic and diluted net loss per share	69,655	68,688	69,414	64,943
(1) Stock-based compensation related to the following:				
Cost of revenues	$ 31	$ 20	$ 98	$ 47
Research and development	1,038	774	3,291	2,084
Selling, general and administrative	497	368	1,720	1,011
Total stock-based compensation	$ 1,566	$ 1,162	$ 5,109	$ 3,142

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)

	Nine months ended September 30,	
	2007	**2006**
Cash flows from operating activities		
Net loss	$ (17,128)	$ (23,576)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,668	1,967
Stock-based compensation	5,109	3,142
Changes in assets and liabilities:		
Accounts receivable	(3,285)	1,017
Inventories	23	(116)
Prepaid expenses and other assets	403	2,440
Accounts payable	(258)	(714)
Accrued liabilities and other long-term liabilities	3,174	1,017
Contract research liability	(88)	(547)
Interest payable on convertible notes	507	532
Deferred revenue	(4,038)	(1,596)
Total adjustments	3,215	7,142
Net cash and cash equivalents used in operating activities	(13,913)	(16,434)
Cash flows from investing activities		
Purchases of property and equipment	(2,132)	(1,694)
Purchases of available for sale securities	(20,720)	(44,275)
Proceeds from sales and maturities of available for sale securities	30,249	33,322
Net cash and cash equivalents provided by (used in) investing activities	7,397	(12,647)
Cash flows from financing activities		
Payments on term loan and equipment financing obligations	(26)	(78)
Net proceeds from issuances of common stock	1,018	1,334
Net cash and cash equivalents provided by financing activities	992	1,256
Net decrease in cash and cash equivalents	(5,524)	(27,825)
Cash and cash equivalents, beginning of the period	41,554	65,542
Cash and cash equivalents, end of the period	$ 36,030	$ 37,717

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 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 September 30, 2007, the operating results for the three and nine months ended September 30, 2007 and 2006, and cash flows for the nine months ended September 30, 2007 and 2006. The condensed balance sheet as of December 31, 2006 has been derived from audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These financial statements and notes should be read in conjunction with the Company s audited financial statements and notes thereto, included in the Company s annual report on Form 10-K filed with the SEC.

The results of operations for the interim periods presented are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year.

Reclassifications

Certain prior period amounts for stock-based compensation related to research and development expense in the footnotes to the financial statements have been reclassified to conform to current period presentation. 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):

	September 30, 2007 (unaudited)	December 31, 2006
Raw materials	$ 183	$ 185
Work in process	692	711
Finished goods	1,152	1,156
Total inventories	$ 2,027	$ 2,052

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS 123(R), *Share-Based Payment,* using the modified prospective transition method. Under that transition method, compensation cost recognized in the three and nine months ended September 30, 2006 and 2007 included: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all share-based payments granted on or after January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). Because the Company elected to use the modified prospective transition method, results for prior periods have not been restated. In March 2005, the SEC issued Staff Accounting Bulletin (SAB) No. 107, which provides supplemental implementation guidance for SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

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The Company estimates the fair value of stock options granted using the Black-Scholes option valuation model. For options granted before January 1, 2006, the Company amortizes the fair value on an accelerated basis. For options granted on or after January 1, 2006, the Company amortizes the fair value on a straight-line basis. All options are amortized over the requisite service periods of the awards, which are generally the vesting periods.

In November 2005, the FASB issued FASB Staff Position No. FAS123(R)-3, Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards (FAS 123(R)-3). We have adopted the simplified method to calculate the beginning balance of the additional paid-in-capital (APIC) pool of the excess tax benefit, and to determine the subsequent impact on the APIC pool and our Statements of Cash Flows of the tax effects of employee stock-based compensation awards that were outstanding upon our adoption of SFAS 123(R).

Revenue Recognition

Revenue from the sale of products is recognized at the time the product is shipped and title transfers to customers, provided no continuing obligation exists and the collectibility 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. Of note, in regard to the Company s collaboration with Nycomed Danmark, APS (Nycomed), in contrast to the Company s other collaborations, because the Company and Nycomed jointly control and fund the development of POSIDUR, as well as share in the risks and rewards of POSIDUR, the Company will not recognize revenue from the reimbursement of qualified research expenses from Nycomed but instead those reimbursements receivable from Nycomed will be recorded as a reduction in research and development expense. 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.

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

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Collaborator				
Endo Pharmaceuticals, Inc. (1)	$ 1,206	$ 1,336	$ 3,705	$ 3,278
Pain Therapeutics, Inc.	734	1,627	2,510	5,744
Nycomed Danmark, APS (2)	763		2,288	
Voyager Pharmaceutical Corporation		116		777
Others	289	79	1,355	465
Total collaborative research and development revenue	$ 2,992	$ 3,158	$ 9,858	$ 10,264

Notes:

(1) Amounts related to the amortization of up-front fees were $547,000 for the three months ended September 30, 2007 and 2006, and $1.6 million for the nine months ended September 30, 2007 and 2006.

(2) Amounts shown include amortization of up-front fees equal to $763,000 and $2.3 million for the three and nine months ended September 30, 2007, respectively. No up-front fees were amortized for Nycomed in the first three and nine months of 2006 since the collaborative agreement with Nycomed was not entered into until November 2006. 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.

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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.

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 the Company s research and development efforts or by events external to the Company, such as regulatory approval to market a product or the achievement of specified sales levels by a third-party collaborator. As such, the milestones are substantially at risk at the inception of the collaboration agreement, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, the Company has no future performance obligations related to that milestone payment.

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. In all cases, revenue is recognized only after a signed agreement is in place.

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, research and development expenses incurred by the Company and reimbursable by Nycomed 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. The research and development expenses associated with the Company s major research and development programs approximate the following (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
POSIDUR (1)	$ 2,092	$ 3,344	$ 8,849	$ 8,543
ELADUR	1,376	1,789	4,027	4,056
TRANSDUR -Sufentanil	730	709	2,263	1,621
Remoxy and other ORADUR-based opioid products licensed to Pain Therapeutics	687	1,213	2,191	4,482
CHRONOGESIC®	289	492	1,633	1,407
Memryte	31	505	1,215	1,051
Others	3,653	1,878	8,662	4,483
Total research and development expenses (2)	$ 8,858	$ 9,930	$ 28,840	$ 25,643

(1) In the three and nine months ended September 30, 2007, research and development expenses for POSIDUR incurred by the Company but reimbursable by Nycomed under the terms of the Company s agreement with Nycomed were $1.1 million and $5.2 million, respectively, which were accounted for as a reduction of research and development expenses. In the three and nine months ended September 30, 2007, research and development expenses for POSIDUR incurred by Nycomed but reimbursable by the Company under the terms of the Company s agreement with Nycomed were $107,000 and $957,000, respectively, which were accounted for as additional research and development expenses. The agreement with Nycomed was not in effect for the first nine months of 2006.

(2) Includes stock-based compensation expenses of $1.0 million and $3.3 million for the three and nine months ended September 30, 2007, respectively, compared to $774,000 and $2.1 million for the corresponding periods in 2006.

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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 (in thousands).

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Net loss	$ (7,882)	$ (8,583)	$ (17,128)	$ (23,576)
Net change in unrealized gain on available-for-sale investments	43	122	56	154
Comprehensive loss	$ (7,839)	$ (8,461)	$ (17,072)	$ (23,422)

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 includes the impact of options to purchase common stock (using the treasury stock method), if dilutive. 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 September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
	(In thousands)		(In thousands)	
Outstanding dilutive securities not included in diluted net loss per share				
Options to purchase common stock	11,609	9,657	11,631	9,407
Convertible notes	11,718	11,853	11,808	15,298
Warrants	1	1	1	1
Total	23,328	21,511	23,440	24,706

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 as rent expense on the condensed statements of operations.

Income taxes

The Company had no income tax expense in the three and nine months ended September 30, 2007 and 2006. As of December 31, 2006, the Company had net operating loss (NOL) carryforwards for federal income tax purposes of approximately $160.0 million, which expire in the years 2018 through 2026 and federal research and development tax credits (R&D credits) of approximately $1.7 million, which expire at various dates beginning in 2018 through 2026, if not utilized. As of December 31, 2006, the Company had NOL carryforwards for state income tax purposes of approximately $82.7 million, which expire in the years 2008 through 2016, and state research and development tax credits of approximately $1.7 million, which do not expire.

Because realization of such tax benefits is uncertain, the Company provided a 100% valuation allowance as of December 31, 2006 and September 30, 2007. Utilization of the NOL and R&D credits carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the

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future provided by Sections 382 and 383 of the Internal Revenue Code of 1986, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credits carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. In addition, the Company issued $60.0 million of convertible notes in 2003 and subsequently converted approximately $26.9 million of these notes as of September 30, 2007 into the Company s stock in 2005, 2006 and 2007. These transactions may also have resulted in a change of control or could result in a change of control in the future upon conversion of the notes to shares and subsequent disposition of the shares.

The Company has not currently completed a study to assess whether a change in control has occurred or whether there have been multiple changes of control since its formation due to the significant complexity and cost associated with such a study and that there could be additional changes in the future. If the Company has experienced a change of control at any time since its formation, utilization of its NOL or R&D credits carryforwards would be subject to an annual limitation under Sections 382 and 383 which is determined by first multiplying the value of the Company s stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D credits carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48. Interest and penalties related to uncertain tax positions will be reflected in income tax expense. Tax years 1998 to 2006 remain subject to future examination by the major tax jurisdictions in which the Company is subject to tax.

Recent Accounting Pronouncements

In February 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. This Statement provides companies an option to measure certain financial instruments at fair value. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the effect of SFAS No. 159 on its financial statements.

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement No. 109 (FIN 48). Under FIN 48, a company would recognize the benefit from a tax position only if it is more-likely-than-not that the position would be sustained upon audit based solely on the technical merits of the tax position. FIN 48 clarifies how a company would measure the income tax benefits from the tax positions that are recognized, provides guidance as to the timing of the derecognition of previously recognized tax benefits and describes the methods for classifying and disclosing the liabilities within the financial statements for any unrecognized tax benefits. FIN 48 also addresses when a company should record interest and penalties related to tax positions and how the interest and penalties may be classified within the income statement and presented in the balance sheet. FIN 48 is effective for fiscal years beginning after December 15, 2006, and has been adopted by the Company effective January 1, 2007. Pursuant to FIN48, the cumulative effects, if any, of applying FIN 48 would be recorded as an adjustment to accumulated deficit as of the beginning of the period of adoption. The Company s adoption of FIN 48 did not have any impact on its financial statements.

Note 2. Strategic Agreements

Agreement with Nycomed

In November 2006, the Company entered into a collaboration agreement with Nycomed. Under the terms of the agreement, the Company licensed to Nycomed the exclusive commercialization rights to POSIDUR for the European Union (EU) and select other countries. Nycomed paid an upfront license fee of $14.0 million, with future potential additional milestone payments of up to $188.0 million upon achievement of defined development, regulatory and sales milestones; of the $188.0 million described above, $8.0 million was recognized as revenue in the second quarter of 2007 due to the achievement of a clinical development milestone and received by the Company in August 2007. The Company is jointly directing and equally funding with Nycomed a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the EU. 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 EU and for adverse product events.

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In contrast to the Company s other collaborations, because the Company and Nycomed jointly control and fund 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. As a result of the collaboration agreement with Nycomed, the Company s research and development expenses were reduced by a net amount of $997,000 and $4.3 million, respectively, for the three and nine months ended September 30, 2007, compared to $0 for the same periods in 2006. The net reduction in research and development expenses for these periods represent a net reimbursement from Nycomed reflecting that both parties bore 50% of the development expenses defined under the collaboration agreement for POSIDUR. In addition, the Company recognized $763,000 and $2.3 million as collaborative research and development revenue for the three and nine months ended September 30, 2007, respectively, from the amortization of the $14.0 million up-front fee paid by Nycomed, while there was no revenue in the corresponding periods in 2006 since the collaborative agreement was not entered into until November 2006.

Agreements with Endo Pharmaceuticals

CHRONOGESIC

In November 2002, the Company entered into a development, commercialization and supply license agreement with Endo Pharmaceuticals, Inc. (Endo) under which the companies will collaborate on the development and commercialization of CHRONOGESIC for the U.S. and Canada. The agreement was amended in January 2004, November 2004, January 2006 and April 2007 to take into account the increase in the CHRONOGESIC development program timeline due to DURECT s implementation of necessary design and manufacturing enhancements. In connection with the execution of the agreement in November 2002, Endo purchased 1,533,742 shares of newly issued common stock of DURECT at an aggregate purchase price of approximately $5.0 million. Under the terms of the agreement, as amended, DURECT will be responsible for CHRONOGESIC s design and development. Endo shall not be responsible for any development costs for the CHRONOGESIC development product prior to May 1, 2008. Commencing on May 1, 2008, unless the agreement is earlier terminated by Endo, Endo will fund 50% of the ongoing development costs and will reimburse the Company for a portion of the Company s prior development costs for the product upon the achievement of certain milestones. Development-based milestone payments made by Endo under this agreement could total up to $52.0 million. Under the agreement, Endo has licensed exclusive promotional rights to the CHRONOGESIC product in the U.S. and Canada. Endo will be responsible for marketing, sales and distribution, including providing specialty sales representatives dedicated to supplying technical and training support for CHRONOGESIC therapy and will pay for product launch costs. The Company will be responsible for the manufacture of the CHRONOGESIC product. If commercialized, the Company will share profits from the commercialization of CHRONOGESIC in the U.S. and Canada with Endo based on the financial performance of the CHRONOGESIC product. The agreement provides each party with specified termination rights. In particular, the agreement can be terminated by Endo in the event that (i) DURECT has not delivered to Endo on or before March 31, 2008 a written notice (Notice) that a human pharmacokinetic trial had been completed with CHRONOGESIC, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the Agreement during the sixty-day period after DURECT s delivery of the Notice, provided, that, in each case Endo delivers to DURECT its written notice of termination prior to April 30, 2008. The Company has not received any payments or recognized any collaborative research and development revenue with respect to CHRONOGESIC under this agreement and its amendments.

TRANSDUR-Sufentanil

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 product candidate (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. In April 2005, Endo paid the Company a $10.0 million upfront, non-refundable 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 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.

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The $10.0 million up-front 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 current product development plan pursuant to the agreement. For each of the three and nine months ended September 30, 2007 and 2006, the Company recognized $547,000 and $1.6 million, respectively, in collaborative research and development revenue related to this upfront fee. Total collaborative research and development revenue under this arrangement was $1.2 million and $3.7 million for the three and nine months ended September 30, 2007, respectively, compared with $1.3 million and $3.3 million for the corresponding periods in 2006.

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 resistant 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 under this arrangement was $734,000 and $2.5 million for the three and nine months ended September 30, 2007, respectively, compared with $1.6 million and $5.7 million in the corresponding periods in 2006.

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 collectibility of amounts owed was not reasonably assured. Total collaborative research and development revenue under this arrangement was $0 for both the three and nine months ended September 30, 2007 compared with $116,000 and $777,000 for the corresponding periods in 2006.

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 is sublicensed to a third party. As a part of the amendment, the Company paid Voyager $1.0 million in cash and forgave approximately $725,000 which was owed to the Company for previously provided services; the $1.0 million was recorded as research and development expense in the first quarter of 2007 and the forgiveness of $725,000 had no impact on the Company s financial statements as this amount had not previously been reflected in the Company s financial statements because collectability was not reasonably assured.

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Agreement with EpiCept Corporation

In December 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.

Agreement with ALZA Corporation

In April 1998, the Company entered into a development and commercialization agreement with ALZA Corporation (ALZA) for certain product development rights, patent rights, and other know-how relating to the DUROS® system. The agreement 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. In consideration for the rights granted by ALZA and subsequent amendments, the Company has issued ALZA a total of 6,600,000 shares of its common stock, and is required to pay ALZA a royalty on the net sales of products and a percentage of up-front license fees, milestone payments, or any other payments or consideration received by the Company, excluding research and development funding, in each case with respect to products developed under the agreement.

The Company did not incur any development expenses for work performed by ALZA in the three and nine months ended September 30, 2007 and 2006.

Note 3. Goodwill and Intangible Assets

Intangible assets consist of the following (in thousands):

	September 30, 2007		
	Gross Intangibles	Accumulated Amortization	Net Intangibles
Developed technology	$ 3,600	$ (3,534)	$ 66
Patents	466	(444)	22
Other intangibles	3,260	(3,260)	
Total	$ 7,326	$ (7,238)	$ 88

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	December 31, 2006		
	Gross Intangibles	Accumulated Amortization	Net Intangibles
Developed technology	$ 3,600	$ (3,517)	$ 83
Patents	466	(438)	28
Other intangibles	3,260	(3,260)	
Total	$ 7,326	$ (7,215)	$ 111

The Company expects to amortize the remaining net intangible assets balance of $88,000 as follows: $8,000 in the three months ending December 31, 2007, $31,000 in each of the years 2008 and 2009, and $18,000 in the year 2010. Should intangible assets become impaired, the Company will write them down to their estimated fair value.

Goodwill totaled $6.4 million at September 30, 2007 and December 31, 2006. In the fourth quarter of 2006, 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. Stock-Based Compensation

As of September 30, 2007, the Company has five stock-based employee compensation plans, which have not changed in 2007. The employee stock-based compensation cost that has been included in the condensed statements of operations was $1.6 million and $5.1 million for the three and nine months ended September 30, 2007, compared to $1.2 million and $3.1 million for the corresponding periods in 2006.

Impact of the Adoption of SFAS 123(R)

See Note 1 for a description of our adoption of SFAS 123(R), *Share-Based Payment,* on January 1, 2006. 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 nine months ended September 30, 2007 and 2006, respectively (in thousands).

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Cost of revenues	$ 31	$ 20	$ 98	$ 47
Research and development	1,038	774	3,291	2,084
Selling, general and administrative	497	368	1,720	1,011
Total stock-based compensation per FAS 123(R)	$ 1,566	$ 1,162	$ 5,109	$ 3,142

As of September 30, 2007 and December 31, 2006, $39,000 and $41,000, respectively, of stock-based compensation cost was capitalized in inventory on the Company s balance sheets.

Determining Fair Value

Valuation and Amortization Method. The Company estimates the fair value of stock options granted using the Black-Scholes option valuation model. For options granted before January 1, 2006, the Company amortizes the fair value on an accelerated basis. For options granted on or after January 1, 2006, the Company amortizes the fair value on a straight-line basis. All options are amortized over the requisite service periods of the awards, which are generally the vesting periods.

Expected Term. The expected term of options granted represents the period of time that the options are expected to be outstanding. Based on the limited historical exercise and post-vesting termination of options granted under the Company s plans, the Company does not believe that it is able to rely on its historical employee exercise behavior to provide accurate data for estimating the Company s expected term for use in determining the fair value of these options. Therefore, as allowed by Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payment*, the

Company has opted to use the simplified method for estimating its expected term equal to the midpoint between the vesting period and the contractual term of the stock options.

Expected Volatility. The Company estimates the volatility of its common stock at the date of grant based on the historical volatility of the Company s common stock, consistent with SFAS 123(R) and SAB 107.

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Risk-Free Rate. The Company bases the risk-free rate that it uses in the Black-Scholes option valuation model on the implied yield in effect at the time of option grant on U.S. Treasury zero-coupon issues with equivalent remaining terms.

Dividends. The Company has never paid any cash dividends on its common stock and the Company does not anticipate paying any cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero in the Black-Scholes option valuation model.

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 nine months ended September 30, 2007 compared to the same periods in 2006:

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Stock options				
Risk-free rate	3.97-4.99%	4.56-4.92 %	3.97-5.16%	4.33-5.11%
Expected dividend yield				
Expected term (in years)	6.25	6.25	6.25	6.25
Volatility	51-85%	92%	51-89%	91-94%
Forfeiture	14.7%	17.2%	14.7%	17.2%

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Employee Stock Purchase Plan				
Risk-free rate	4.63-5.01%	4.94-4.98 %	4.63-5.01%	4.25-4.98%
Expected dividend yield				
Expected term (in years)	1.25	1.25	1.25	1.25
Volatility	50-59%	54-82%	50-59%	53-89%
Forfeiture				

Note 5. Conversion of Convertible Subordinated Notes

In September 2007, two holders of the Company s 6.25% Convertible Subordinated Notes due June 2008 (the Notes) converted $4.2 million in principal amount of Notes into 1,330,793 shares of common stock at the conversion rate originally set forth in the indenture for such Notes. Under the terms of the exchange agreements between the Company and the holders, the Company made cash payments to such holders of $293,440 which satisfied the future interest payments due on such Notes until maturity of $262,000 plus a small premium for early conversion. As a result of the conversions, the Company recorded $223,000 in debt conversion expense in its statement of operations for the three and nine months ended September 30, 2007. The debt conversion expense represents the difference between our cash payment of $293,440 to the holders and the interest expense accrued on the $4.2 million of notes converted from the last interest payment date to the dates of conversions. The conversions were recorded as a reduction of $4.2 million of short-term liabilities, a reduction of other short-term assets of $41,000 attributable to the related unamortized debt issuance costs and an increase of $4.2 million to shareholders equity. As of September 30, 2007, the remaining principal balance of our convertible subordinated notes was $33.1 million, which is due on June 15, 2008. See Note 6.

Note 6. Subsequent Event

In October 2007, the Company entered into privately negotiated transactions with additional holders of its Notes, pursuant to which such holders elected to convert $9.5 million in principal amount of such Notes into an aggregate of 3,030,472 shares of common stock, at the conversion rate originally set forth in the indenture for such Notes. The Company made cash payments to such holders of $688,450, which amount satisfies the future interest payments due on such Notes until maturity of $596,625 plus a small premium for early conversions. Following such conversions, the aggregate principal amount of outstanding Notes is $23.6 million as of October 31, 2007.

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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 nine months ended September 30, 2007 and 2006 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. When used in this report or elsewhere by management from time to time, the words believe, anticipate, intend, plan, estimate, expect, and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations. 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. 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 commercializing pharmaceutical systems that will deliver the right drug to the right place in the right amount at the right time to treat chronic or episodic diseases and conditions. By integrating chemistry and engineering advancements, we seek to achieve what drugs or devices alone cannot. Our pharmaceutical systems enable optimized therapy for a given disease or patient population by controlling the rate and duration of drug administration and delivering drug to its intended site of action.

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 disclosed seven product candidates in research and development of which six are in collaboration with third-party pharmaceutical companies. The following are our publicly announced product candidates in development:

POSIDUR

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

In January 2006, the U.S. Investigational New Drug (IND) application for POSIDUR was accepted by the U.S. Food and Drug Administration (FDA). In April 2006, we announced the results from our first Phase II clinical study in hernia patients conducted in Australia. In the second quarter of 2006, we expanded the development of POSIDUR into multiple on-going Phase II clinical trials in the U.S. and in other countries in a variety of surgical procedures for the purpose of selecting the optimal dosing and the surgical procedures for our pivotal Phase III trials.

In November 2006, we entered into a collaboration agreement with Nycomed. Under the terms of the agreement, we licensed to Nycomed the exclusive commercialization rights to POSIDUR for the EU and select other countries. Nycomed paid us an upfront license fee of $14.0 million, with future potential additional milestone payments as of signing of up to $188.0 million upon achievement of defined development, regulatory and sales milestones; of the $188.0 million described above, $8.0 million was recognized as revenue in the second quarter of 2007 due to the achievement of a clinical development milestone and received by us in August 2007. We are jointly directing and equally funding with Nycomed a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the EU. 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 other countries.

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

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In July 2007, we announced positive results from a 122 patient Phase IIb clinical trial of POSIDUR for treatment of post-operative pain in patients undergoing inguinal hernia repair and provided an update to our Phase II program (description below). The Phase IIb trial was designed to be the study upon which we and our collaborator Nycomed would base our decision for advancing POSIDUR into Phase III clinical trials. 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 an $8.0 million milestone payment by Nycomed to us under the parties collaborative agreement, which we recognized as milestone revenue in the second quarter of 2007. We received the cash payment of the $8.0 million in August 2007. We held an end-of-Phase II meeting with the U.S. Food & Drug Administration (FDA) in the third quarter of 2007 and are in dialogue with the FDA regarding our anticipated POSIDUR Phase III program. Hospira, our manufacturer of POSIDUR, has produced supplies for ICH stability and validation studies and Phase III clinical trials.

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. Hernia and shoulder studies have been completed while an appendectomy study is on-going. 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.

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

In December 2002, we entered into an agreement with Pain Therapeutics, amended in December 2005, under which we granted Pain Therapeutics the exclusive, worldwide right to develop and commercialize selected long-acting oral opioid products using our ORADUR technology incorporating four specified opioid drugs. The first product being developed under the collaboration is Remoxy, a novel long-acting oral formulation of the opioid oxycodone targeted to decrease the potential for oxycodone abuse. Remoxy is intended for patients with chronic pain. In February 2006, Pain Therapeutics and its sublicensee King Pharmaceuticals, Inc. (King) reported that Remoxy had successfully completed a Special Protocol Assessment (SPA) with the FDA. According to Pain Therapeutics and King, the Remoxy Phase III pivotal study is now fully enrolled and top-line results of this study are expected in the fourth quarter of 2007.

During 2006, we also worked with King and Pain Therapeutics on the development of a second ORADUR abuse-resistant opioid product. In August 2006, King and Pain Therapeutics announced the initiation of a Phase I clinical trial for this ORADUR-based opioid drug candidate, and that the IND application for this drug candidate had been accepted by the FDA. In November 2006, Pain Therapeutics announced positive results from that Phase I clinical trial.

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 1/5th the size of currently marketed transdermal fentanyl patches for a therapeutically equivalent dose) may offer improved convenience and compliance for patients. In February 2005, we commenced an open label Phase II clinical trial using patches manufactured by us to evaluate the transition of chronic pain patients from Duragesic® to TRANSDUR-Sufentanil, and announced positive preliminary results from the trial in December 2005. In March 2005, we entered into an agreement with Endo granting Endo exclusive rights to develop, market and commercialize TRANSDUR-Sufentanil in the U.S. and Canada. Endo is currently conducting the clinical program for TRANSDUR-Sufentanil. 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 various opioids to TRANSDUR-Sufentanil in the second quarter of 2007.

ELADUR

ELADUR uses our proprietary TRANSDUR transdermal technology and is intended to provide continuous delivery of bupivacaine for up to three days from a single application, as compared to a wearing time limited to 12 hours with currently available lidocaine patches. In December 2006, we announced that we had successfully completed Phase I clinical trials with ELADUR. DURECT s Phase II program for ELADUR has begun in the U.S. under an IND application with a randomized, multi-center, double-blind, placebo controlled, two-way crossover Phase IIa trial in approximately 50 patients with Post-Herpetic Neuralgia (PHN) to assess safety as well as the magnitude, duration and characteristics of analgesic activity of ELADUR.

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During the first nine months of 2007, we continued to enroll patients in the Phase IIa trial and jointly conducted manufacturing development activities with Corium International, Inc., whom we have contracted to manufacture clinical and commercial supplies of ELADUR. As of the date of this report, we have completed enrollment of our Phase IIa study, and we expect to report data from this Phase IIa study by the end of 2007.

Memryte

In July 2002, we entered into a development and commercialization agreement 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. Effective January 2007, we amended our agreement with Voyager. Under the amendment, among other changes to the agreement, the royalty rate that we will receive on net sales of Memryte, if commercialized, was doubled (to 10-14% of net sales after the amendment), and in addition, we will receive 10% of any upfront, milestone and other fees received by Voyager in the event that the product is sublicensed to a third party. In return, we paid Voyager $1.0 million in cash and forgave approximately $725,000 which was owed to us for previously provided services.

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. See Risk Factors *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.*

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 have granted to Endo exclusive commercialization rights for CHRONOGESIC in the U.S. and Canada. In 2002, we completed a pilot Phase III clinical trial for CHRONOGESIC. Clinical trials have been suspended pending system redesign which is on-going.

DURECT Research Programs

We are also currently researching and developing, by ourselves and in conjunction with third party pharmaceutical and biotechnology companies, additional pharmaceutical systems in a variety of therapeutic areas, including chronic pain, central nervous system disorders and cardiovascular disease based on our proprietary drug delivery platform technologies. We have active programs underway to apply our drug delivery systems to various small molecule and biologic drug candidates, and have entered into a number of feasibility studies with biotechnology and pharmaceutical companies to test their products in our systems.

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) milestone payments, and (c) the reimbursement of qualified research expenses by the third party. Before we signed the collaboration agreement with Nycomed in November 2006, we generated substantially all collaborative research and development revenues from three collaborative agreements related to TRANSDUR-Sufentanil, Remoxy and other specified ORADUR-based oral opioids, and Memryte. Due to the signing of the Nycomed agreement related to POSIDUR, we recognized collaborative research and development revenue from the amortization of the upfront payment of $14.0 million received from Nycomed and during the second quarter of 2007, we recognized $8.0 million of milestone revenue pursuant to this agreement. However, 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 by Nycomed. Rather, research and development expenses incurred by us in conjunction with the Nycomed collaboration and reimbursable by Nycomed are recorded as a reduction in research and development expense.

Product Revenues

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

ALZET® osmotic pumps and accessories for animal research use; and

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

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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 partners to develop product candidates based on our drug delivery technologies.

Since our inception in 1998, we have had a history of operating losses. At September 30, 2007, we had an accumulated deficit of $232.5 million. Our net loss for the three and nine months ended September 30, 2007 was $7.9 million and $17.1 million, respectively. Our losses were $33.3 million, $18.1 million and $27.6 million for the twelve months ended December 31, 2006, 2005 and 2004, 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 pre-clinical studies, clinical trials and other research and development activities as well as to incur additional stock-based compensation cost related to research and development personnel under SFAS 123(R). We expect selling, general and administrative expenses to increase in the near future due to expected increases in employee related costs to support our current business activities and in stock-based compensation cost related to selling, general and administrative personnel under SFAS 123(R). We also expect to incur non-cash expenses relating to amortization of intangible assets. We do not anticipate revenues from our pharmaceutical systems, should they be approved, for several years. Therefore, we expect to incur continuing losses and negative cash flow from operations for the foreseeable future.

Critical Accounting Policies and Estimates

General

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. The most significant estimates and assumptions relate to revenue recognition, the recoverability of our long-lived assets, including goodwill and other intangible assets, accrued liabilities, contract research liabilities and stock-based compensation. Actual amounts could differ significantly from these estimates.

Revenue Recognition

Revenue from the sale of products is recognized when there is persuasive evidence that an arrangement exists, the product is shipped and title transfers to customers, provided no continuing obligation exists, the price is fixed or determinable and the collectibility of the amounts owed is reasonably assured. 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 our continuing involvement with the third party collaborator pursuant to the applicable agreement. Such period generally represents the research and development period set forth in the work plan defined in the respective agreements between us and our third-party collaborators.

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

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

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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. In all cases, revenue is recognized only after a signed agreement is in place.

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, research and development expenses incurred by the Company and reimbursable by Nycomed 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.

Intangible Assets and Goodwill

We record intangible assets when we acquire other companies. The cost of an acquisition is allocated to the assets acquired and liabilities assumed, including intangible assets, with the remaining amount being classified as goodwill. Certain intangible assets such as completed or core technologies are amortized over time, while acquired in-process research and development is recorded as a one-time charge on the acquisition date. Acquired in-process research and development represents the value of research projects in process at the time of acquisition which have not yet reached technological feasibility and which have no alternative future use. The determination of the amount of acquired in-process research and development involves several estimates and judgments, including the percentage of completion of the in-process technology and assumptions about future cash flows to be derived from the technology and discount rates. Different assumptions employed in determining the value of in-process research and development could result in a greater or lesser amount being recorded.

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

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

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

We perform a review for impairment of goodwill at least annually in accordance with SFAS 142, *Goodwill and Other Intangible Assets*. No impairment of goodwill has been recorded through December 31, 2006. However, there can be no assurance that at the time other periodic reviews are completed, a material impairment charge will not be recorded.

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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

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R), *Share-Based Payment,* using the modified prospective transition method. Under that transition method, compensation expense that we recognize beginning on that date includes: (a) compensation expense for all share-based payments granted prior to, but not yet vested as of, January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation expense for all share-based payments granted on or after January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). Because we elected to use the modified prospective transition method, results for prior periods have not been restated.

We estimate the fair value of options granted using the Black-Scholes option valuation model. As allowed by Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payment,* we have opted to use the simplified method for estimating our expected term equal to the midpoint between the vesting period and the contractual term of our stock options. We estimate the volatility of our common stock at the date of grant based on the historical volatility of our common stock, consistent with SFAS 123(R) and SAB 107. We base the risk-free rate that we use in the Black-Scholes option valuation model on the implied yield in effect at the time of option grant on U.S. Treasury zero-coupon issues with equivalent remaining terms. We have never paid any cash dividends on our common stock and we do not anticipate paying any cash dividends in the foreseeable future. Consequently, we use an expected dividend yield of zero in the Black-Scholes option valuation model. SFAS 123(R) requires us to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. For options granted before January 1, 2006, we amortize the fair value on an accelerated basis. For options granted on or after January 1, 2006, we amortize the fair value on a straight-line basis. All options are amortized over the requisite service periods of the awards, which are generally the vesting periods. We may elect to use different assumptions under the Black-Scholes option valuation model in the future, which could materially affect our net income or loss and net income or loss per share.

Recent Accounting Pronouncements

In February 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. This Statement provides companies an option to measure certain financial instruments at fair value. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We are currently assessing the effect of SFAS No. 159 on our financial statements.

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement No. 109 (FIN 48). Under FIN 48 a company would recognize the benefit from a tax position only if it is more-likely-than-not that the position would be sustained upon audit based solely on the technical merits of the tax position. FIN 48 clarifies how a company would measure the income tax benefits from the tax positions that are recognized, provides guidance as to the timing of the derecognition of previously recognized tax benefits and describes the methods for classifying and disclosing the liabilities within the financial statements for any unrecognized tax benefits. FIN 48 also addresses when a company should record interest and penalties related to tax positions and how the interest and penalties may be classified within the income statement and presented in the balance sheet. FIN 48 is effective for fiscal years beginning after December 15, 2006, and has been adopted by us effective January 1, 2007. Pursuant to FIN 48, the cumulative effects, if any, of applying FIN 48 would be recorded as an adjustment to accumulated deficit as of the beginning of the period of adoption. The adoption of FIN 48 did not have any impact on our financial statements.

Results of Operations

Three and nine months ended September 30, 2007 and 2006

Revenues. Net revenues were $4.9 million and $24.1 million in the three and nine months ended September 30, 2007, respectively, compared to $5.1 million and $16.5 million for the corresponding periods in 2006. The decrease in total revenues for the three months ended September 30, 2007 is primarily attributable to lower collaborative research and development revenue from Pain Therapeutics, Endo Pharmaceuticals and Voyager compared to the same period in 2006, partially offset by increased revenues related to the amortization of our upfront payment received from Nycomed in the fourth quarter of 2006 and increased revenues from feasibility agreements. The increase in total revenues for the nine

months ended September 30, 2007 is primarily attributable to milestone revenue of $8.0 million recognized from our Nycomed collaboration related to POSIDUR as well as increased collaborative research and development revenue from Endo, from feasibility agreements with third parties and from the amortization of the Nycomed upfront fee, partially offset by lower collaborative research and development revenue from Pain Therapeutics and Voyager compared to the same period in 2006.

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Collaborative research and development revenue

We recognize revenue from collaborative research and development activities and service contracts. We recorded $3.0 million and $9.9 million of collaborative research and development revenue for the three and nine months ended September 30, 2007, respectively, compared to $3.2 million and $10.3 million for the corresponding periods in 2006. Collaborative research and development revenue represents reimbursement of qualified expenses related to the collaborative agreements with various third parties to research, develop and commercialize potential products using our drug delivery technologies, and revenue recognized from amortization of upfront fees. The decrease in collaborative research and development revenue in the three months ended September 30, 2007 compared with the same period in 2006 was primarily attributable to our decreased development activities for Remoxy and other opioids (collaboration with Pain Therapeutics), TRANSDUR-Sufentanil (collaboration with Endo) and Memryte (collaboration with Voyager), partially offset by higher revenue recognized from amortization of the upfront fees received from Nycomed in connection with our agreement for POSIDUR, and higher collaborative research and development revenue recognized in connection with feasibility agreements. The decrease in collaborative research and development revenue in the nine months ended September 30, 2007 compared with the same period in 2006 was primarily attributable to our decreased development activities for Remoxy and other opioids (collaboration with Pain Therapeutics) and Memryte (collaboration with Voyager), partially offset by higher revenue recognized from amortization of the upfront fee received from Nycomed in connection with our agreement for POSIDUR, and higher collaborative research and development revenue recognized in connection with increased development activities associated with TRANSDUR-Sufentanil (collaboration with Endo) and feasibility agreements.

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 nine months ended September 30, 2007 and 2006, we recognized $547,000 and $1.6 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 three and nine months ended September 30, 2007 as collaborative research and development revenue from the amortization of the up-front fee was $763,000 and $2.3 million, respectively, and no such revenue was recognized in the same periods in 2006. The term of the continuing involvement has been estimated based on the current product development plan pursuant to the agreement.

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 September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
Collaborator				
Endo (1)	$ 1,206	$ 1,336	$ 3,705	$ 3,278
Pain Therapeutics	734	1,627	2,510	5,744
Nycomed (2)	763		2,288	
Voyager		116		777
Others	289	79	1,355	465
Total collaborative research and development revenue	$ 2,992	$ 3,158	$ 9,858	$ 10,264

Notes:

(1) Amounts related to the amortization of up-front fees were $547,000 for the three months ended September 30, 2007 and 2006, and $1.6 million for the nine months ended September 30, 2007 and 2006.

(2) Amounts shown include the amortization of up-front fees equal to $763,000 and $2.3 million for the three and nine months ended September 30, 2007, compared with $0 for both the three and nine months ended September 30, 2006, respectively. Research and development expenses incurred by us in conjunction with the Nycomed collaboration and reimbursable by Nycomed are recorded as a reduction to total research and development expense.

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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 revenue

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 the Company s research and development efforts or by events external to the Company, such as regulatory approval to market a product or the achievement of specified sales levels by a third-party collaborator. As such, the milestones are substantially at risk at the inception of the collaboration agreement, and the amounts of the payments assigned thereto are commensurate with the milestone achieved. In addition, upon the achievement of a milestone event, the Company has no future performance obligations related to that milestone payment. We recorded $0 and $8.0 million of milestone revenue for the three and nine months ended September 30, 2007, respectively, compared to $0 for each of the corresponding periods in 2006. The milestone in 2007 was recorded in the second quarter due to the achievement of a clinical development milestone for POSIDUR; we received the $8.0 million milestone payment from Nycomed in August 2007.

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 products. Net product revenues were $1.9 million and $6.2 million in the three and nine months ended September 30, 2007, respectively, compared to $2.0 million and $6.2 million for the corresponding periods in 2006.

Cost of revenues. Cost of revenues was $780,000 and $2.4 million for the three and nine months ended September 30, 2007, respectively, compared to $666,000 and $2.3 million for the corresponding periods in 2006. Cost of revenues includes cost of product revenue from our ALZET product line and our LACTEL polymer product line. The increases in cost of revenues for our existing commercial product lines for the three and nine months ended September 30, 2007 were primarily due to certain inventory write-offs related to our LACTEL product line incurred in the third quarter of 2007 compared with the same periods of 2006. Stock based compensation expense recognized under SFAS 123(R) related to cost of revenue was $31,000 and $98,000 for the three and nine months ended September 30, 2007, respectively, compared with $20,000 and $47,000 for the corresponding periods in 2006. We had 22 manufacturing employees as of September 30, 2007, which was the same number as of September 30, 2006. We expect cost of revenues to remain comparable in the near future, as we do not expect product revenues to change significantly in the near future.

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 $8.9 million and $28.8 million for the three and nine months ended September 30, 2007, respectively, compared to $9.9 million and $25.6 million for the corresponding periods in 2006. The decrease in research and development expenses in the three months ended September 30, 2007 was primarily attributable to lower development expenses for POSIDUR, Remoxy and other ORADUR-based opioid product candidates, ELADUR, Memryte and CHRONOGESIC compared with the same period in 2006, partially offset by an increase in other research programs The increase in the nine months ended September 30, 2007 was primarily attributable to higher employee costs and higher development expenses for TRANSDUR-Sufentanil, POSIDUR, Memryte, CHRONOGESIC and other research programs, partially offset by lower development expenses for Remoxy and other ORADUR-based opioid product candidates, compared with the same period in 2006; the 2007 figures include our recording $1 million in research and development expense associated with our payment of $1.0 million to Voyager in connection with our amended agreement with Voyager in the first quarter of 2007. Stock based compensation expense recognized under SFAS 123(R) related to research and development personnel was $1.0 million and $3.3 million for the three and nine months ended September 30, 2007, respectively, and $774,000 and $2.1 million for the corresponding periods in 2006.

POSIDUR

In the three months ended September 30, 2007, our research and development expenses for POSIDUR decreased by $1.3 million compared to the same period in 2006 due primarily to a decrease in clinical costs associated our Phase II clinical program due to the completion of the majority of these trials and a net reduction of $997,000 in research and development expense related to POSIDUR under our agreement with Nycomed during this period. In the nine months ended September 30, 2007, our research and development expenses for POSIDUR increased by $306,000 compared to the same period in 2006 due to an increase in costs associated with the Phase II clinical program and contract manufacturing development activities; these figures reflect that we recorded a net reduction of $4.3 million in research and development expense related to POSIDUR under our agreement with Nycomed for this period.

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Research and development expenses for POSIDUR incurred by us but reimbursable by Nycomed under the terms of our agreement with Nycomed were $1.1 million and $5.2 million in the three and nine months ended September 30, 2007, respectively, and $0 for each of the corresponding periods in 2006, which was 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 $107,000 and $957,000 in the three and nine months ended September 30, 2007, and $0 for each of the corresponding periods in 2006, which was 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 $997,000 and $4.3 million for the three and nine months ended September 30, 2007, respectively, compared to $0 for the same periods in 2006. 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.

TRANSDUR-Sufentanil

Our research and development expenses for TRANSDUR-Sufentanil increased by $21,000 in the three months ended September 30, 2007 compared with the same period of 2006 primarily due to slightly higher clinical manufacturing related activities performed in support of this product candidate. Our research and development expenses for TRANSDUR-Sufentanil increased by $642,000 in the nine months ended September 30, 2007 compared with the same period of 2006 primarily due to increased clinical manufacturing related activities performed in support of this product candidate.

Remoxy and other ORADUR-based opioid products

Our research and development expenses for Remoxy and other opioids partnered with Pain Therapeutics decreased by $526,000 in the three months ended September 30, 2007 compared with the same period of 2006 due to reduced formulation and clinical manufacturing activities for Remoxy on our part. Our research and development expenses for Remoxy and other opioids partnered with Pain Therapeutics decreased by $2.3 million in the nine months ended September 30, 2007 compared with the same period of 2006 due to reduced formulation and clinical manufacturing activities for Remoxy and other ORADUR-based opioid projects performed by us.

Memryte

Our research and development expenses for Memryte decreased by $474,000 in the three months ended September 30, 2007 compared with the same period of 2006 since we stopped essentially all development activities for Memryte in 2007. Our research and development expenses for Memryte increased by $164,000 in the nine months ended September 30, 2007 compared with the same period of 2006 primarily because the reported research and development expense in 2007 includes a one-time cash payment of $1.0 million which we made in January 2007 in accordance with our amended license agreement with Voyager.

CHRONOGESIC® (sufentanil) Pain Therapy System

Our research and development expenses for CHRONOGESIC decreased by $203,000 in the three months ended September 30, 2007 compared with the same period of 2006 primarily due to lower external development expenses in the third quarter of 2007. Our research and development expenses for CHRONOGESIC increased by $226,000 in the nine months ended September 30, 2007 compared with the same period of 2006 primarily due to increased externally contracted studies in the nine months of 2007.

ELADUR

Our research and development expenses for ELADUR decreased by $413,000 in the three months ended September 30, 2007 compared with the same period of 2006 primarily due to lower contract manufacturing expenses in the third quarter of 2007. Our research and development expenses for ELADUR decreased by $29,000 in the nine months ended September 30, 2007 compared with the same period of 2006 primarily due to lower contract manufacturing expenses, partially offset by higher clinical trials expenses for a Phase II clinical trial in 2007.

Other DURECT Research Programs

Our research and development expenses for all other activities increased by $1.8 million in the three months ended September 30, 2007 compared with the same period of 2006 primarily due to higher employee related costs and increased formulation development activities for other product candidates. Our research and development expenses for all other activities increased by $4.2 million in the nine months ended September 30, 2007 compared with the same period of 2006 primarily due to higher employee related costs and increased formulation development activities for other product candidates.

As of September 30, 2007, we had 112 research and development employees compared with 114 as of the corresponding date in 2006. We expect research and development expenses to increase in the near future as we continue product development efforts for our internal and partnered product candidates and incur additional stock-based compensation costs related to research and development personnel under SFAS 123(R).

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

	Three months ended September 30,		Nine months ended September 30,	
	2007	2006	2007	2006
POSIDUR (1)	$ 2,092	$ 3,344	$ 8,849	$ 8,543
ELADUR	1,376	1,789	4,027	4,056
TRANSDUR-Sufentanil	730	709	2,263	1,621
Remoxy and other ORADUR-based opioid products licensed to Pain Therapeutics	687	1,213	2,191	4,482
CHRONOGESIC	289	492	1,633	1,407
Memryte	31	505	1,215	1,051
Others	3,653	1,878	8,662	4,483
Total research and development expenses (2)	$ 8,858	$ 9,930	$ 28,840	$ 25,643

(1) In the three and nine months ended September 30, 2007, research and development expenses for POSIDUR incurred by us but reimbursable by Nycomed under the terms of our agreement with Nycomed were $1.1 million and $5.2 million, respectively, which were accounted for as a reduction of research and development expenses. In the three and nine months ended September 30, 2007, research and development expenses for POSIDUR incurred by Nycomed but reimbursable by us under the terms of our agreement with Nycomed were $107,000 and $957,000, respectively, which were accounted for as additional research and development expenses. The agreement with Nycomed was not in effect for the first nine months of 2006.

(2) Includes stock-based compensation expenses of $1.0 million and $3.3 million for the three and nine months ended September 30, 2007, respectively, compared to $774,000 and $2.1 million for the corresponding periods in 2006.

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

Selling, General and Administrative. Selling, general and administrative expenses are primarily comprised of salaries 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 $3.1 million and $10.4 million for the three and nine months ended September 30, 2007, respectively, compared to $3.3 million and $9.5 million for the corresponding periods in 2006. The decrease in selling, general and administrative expenses in the three months ended September 30, 2007 compared with the same period in 2006 was primarily attributable to lower consulting expenses related to Sarbanes-Oxley compliance and lower recruiting expenses. The increase in selling, general and administrative expenses in the nine months ended September 30, 2007 compared with the same period in 2006 was primarily attributable to higher employee related costs, patent related expenses and stock based compensation expense. Stock-based compensation expense recognized under SFAS 123(R) related to selling, general and administrative personnel was $497,000 and $1.7 million for the three and nine months ended September 30, 2007, respectively, compared to $368,000 and $1.0 million for the corresponding periods in 2006.

As of September 30, 2007, we had 37 selling, general and administrative personnel compared with 36 as of the corresponding date in 2006. We expect selling, general and administrative expenses to increase in the near future due to expected increases in employee related costs to support our current business activities and in stock-based compensation cost related to selling, general and administrative personnel under SFAS 123(R).

Amortization of intangible assets. Amortization of intangible assets was $8,000 and $23,000 for the three and nine months ended September 30, 2007, respectively, compared to $22,000 and $416,000 for the corresponding periods in 2006. The amortization of intangible assets decreased in the three and nine months ended September 30, 2007 as certain intangible assets were fully amortized in 2006. We continue to amortize the existing intangible assets at a constant rate over their estimated useful lives. In 2006, 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.

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The net amount of other intangible assets at September 30, 2007 was $88,000, which will be amortized as follows: $8,000 for the remaining three months ending December 31, 2007, $31,000 in each of the years ending December 31, 2008 and 2009, and $18,000 for the year ending December 31, 2010. We periodically evaluate acquired intangible assets for impairment or obsolescence. Should the intangible assets become impaired or obsolete, we will write them down to their estimated fair value.

Other Income (Expense). Interest and other income was $906,000 and $2.8 million for the three and nine months ended September 30, 2007, respectively, compared to $957,000 and $2.8 million for the corresponding periods in 2006. The slight decrease in interest income during the three months ended September 30, 2007 was primarily the result of lower average cash and investment balances as compared to the three months ended September 30, 2006. Interest income remained comparable for the nine months ended September 30, 2007 and 2006 due to higher yields in our investments offset by lower average cash and investment balances in the first nine months of 2007, compared to the same period in 2006.

Interest expense was $716,000 and $2.2 million for the three and nine months ended September 30, 2007, respectively, compared to $710,000 and $2.7 million for the corresponding periods in 2006. The interest expense was primarily due to the interest accrued on our 6.25% convertible notes due in June 2008. The slight increase in interest expense in the three months ended September 30, 2007 was primarily due to slightly higher amortization expenses related to the notes issuance cost, partially offset by the lower debt balance of the convertible notes at September 30, 2007 compared to the same period in 2006. The decrease in interest expense in the nine months ended September 30, 2007 was primarily due to a lower remaining balance on our convertible notes in the nine months ended September 30, 2007 as compared to the same period in 2006. In September 2007, $4.2 million in aggregate principal amount of the convertible notes was converted into 1.3 million shares of our common stock at the exchange rate in the indenture.

Debt conversion expense was $223,000 for each of the three and nine months ended September 30, 2007 compared to $0 and $2.3 million in the same periods in 2006. The debt conversion expense in the third quarter of 2007 was recorded in connection with the conversion of $4.2 million in aggregate principal amount of the 6.25% convertible notes into 1.3 million shares of our common stock in September 2007. The debt conversion expense in the second quarter of 2006 was recorded in connection with the conversion of $20.0 million in aggregate principal amount of the 6.25% convertible notes into 6.3 million shares of our common stock in May 2006.

Liquidity and Capital Resources

We had cash, cash equivalents and investments totaling $66.6 million at September 30, 2007 compared to $81.6 million at December 31, 2006. These balances include $1.3 million of interest-bearing marketable securities classified as restricted investments on our balance sheets as of September 30, 2007 and December 31, 2006. The decrease in cash, cash equivalents and investments during the nine months ended September 30, 2007 was primarily the result of ongoing operating expenses, partially offset by payments received from customers and collaborators.

Working capital was $24.2 million and $63.1 million at September 30, 2007 and December 31, 2006, respectively. The decrease was primarily attributable to the inclusion as short-term liabilities of $33.1 million of convertible notes due in June 2008 and our operating expenditures in the nine months ended September 30, 2007.

We used $13.9 million of cash in operating activities for the nine months ended September 30, 2007 compared to $16.4 million for the corresponding period in 2006. 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 receipt of an $8.0 milestone payment from Nycomed in the third quarter of 2007, partially offset by increases in operating expenses and accounts receivable from our third party collaborators for the nine months ended September 30, 2007 compared to the same period in 2006.

We received $7.4 million of cash provided by investing activities for the nine months ended September 30, 2007 compared to $12.6 million of cash used in investing activities in the corresponding period in 2006. The increase in cash provided by investing activities was primarily due to a decrease in purchases of short-term and long-term investments net of proceeds from maturities of these investments, partially offset by increased purchases of property and equipment for the nine months ended September 30, 2007 compared to the same period in 2006.

We received $992,000 of cash provided by financing activities for the nine months ended September 30, 2007 compared to $1.3 million for the corresponding period in 2006. The decrease was primarily due to lower proceeds from exercises of stock options in the nine months ended September 30, 2007 compared to the same period in 2006.

In October 2005, we filed a shelf registration statement on Form S-3 with the SEC, which will allow us to offer up to $75.0 million of securities from time to time in one or more public offerings of our common stock. In November 2005, we closed a follow-on public offering of 8,183,274 shares of our common stock at $5.00 per share and received net proceeds of approximately $38.1 million, after deducting underwriting discounts

and related expenses.

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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. The notes bear interest at a fixed rate of 6.25% per annum and are due on June 15, 2008. The notes are 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, subject to adjustment in certain circumstances. Interest on the notes is payable semi-annually in arrears in June and December. We received net proceeds of approximately $56.7 million after deducting underwriting fees of $3.0 million and related expenses of $300,000. The convertible subordinated notes are unsecured obligations of ours and are subordinate to any secured debt we currently have or any future senior debt we may have. The proceeds from the convertible notes will be used to fund the research, development, manufacture and commercialization of existing and future products and for general corporate purposes, including working capital and capital expenditures. In the third quarter of 2005, we exchanged $2.7 million in principal amount of our 6.25% convertible subordinated notes with our note holders for 911,730 shares of our common stock as originally set forth in the indenture for such notes. In May 2006, a holder of $20.0 million in principal amount of our 6.25% convertible subordinated notes converted such notes into an aggregate of 6,349,206 shares of common stock, as originally set forth in the indenture for such Notes. We made a cash payment to such holder of $2.9 million, which amount represented a negotiated inducement fee based on a discounted value of future interest payments due on such Notes until maturity. In September 2007, two holders of our Notes converted $4.2 million in principal amount of the Notes into an aggregate of 1,330,793 shares of common stock, as originally set forth in the indenture for such Notes. We made a cash payment to such holders of $293,440, which amount satisfies the future interest payment due on such notes until maturity of $262,000 plus a small premium for early conversions. As of September 30, 2007, the remaining principal balance of our Notes was $33.1 million, which is due on June 15, 2008. In October 2007, we entered into privately negotiated transactions with additional holders of our Notes, pursuant to which such holders elected to convert $9,546,000 in principal amount of such Notes into an aggregate of 3,030,472 shares of common stock, at the conversion rate originally set forth in the indenture for such Notes. We made cash payments to such holders of $688,450, which amount satisfies the future interest payments due on such Notes until maturity of $596,625 plus a small premium for early conversions. Following such conversions, the aggregate principal amount of outstanding Notes is $23.6 million as of October 31, 2007. We may enter into similar transactions from time to time with holders of our convertible notes if we are able to do so on acceptable terms and depending on capital markets conditions.

In conjunction with the acquisition of Southern BioSystems, Inc. (SBS) in April 2001, we assumed bonds (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 September 30, 2007, the remaining principal payments of the bonds were $675,000.

We anticipate that cash used in operating and investing activities will increase in the near future as we continue to research, develop and manufacture our products through internal efforts and partnering activities, and service our debt obligations. During the nine months ended September 30, 2007, 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, 2006.

We also 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 finance our planned operations and 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 revenues from our pharmaceutical systems currently under development for at least the next several years. Accordingly, we may be required to raise additional capital through a variety of sources, including:

collaborative arrangements;

the public equity market;

private equity financing; and/or

public or private debt.

There can be no assurance that 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, any 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.

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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.

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 objective. As of September 30, 2007, approximately 95% of our investment portfolio is composed of investments with original maturities of one year or less and approximately 52% 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 September 30, 2007 by year of maturity (dollars in thousands):

	2007	2008	2009	Total
Cash equivalents:				
Fixed rate	$ 10,236	$	$	$ 10,236
Average fixed rate	4.89%			4.89%
Variable rate	$ 23,160	$	$	$ 23,160
Average variable rate	5.24%			5.24%
Short-term investments:				
Fixed rate	$ 8,197	$ 19,117	$	$ 27,314
Average fixed rate	5.29%	6.14%		5.88%
Long-term investments:				
Fixed rate	$	$ 1,983	$	$ 1,983
Average fixed rate		5.12%		5.12%
Restricted investments:				
Fixed rate	$ 1,283	$	$	$ 1,283
Average fixed rate	3.45%			3.45%
Total investment securities	$ 42,876	$ 21,100	$	$ 63,976
Average rate	4.80%	5.99%		5.31%

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ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures: The Company s principal executive and financial officers reviewed and evaluated the Company s disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 10-Q. Based on that evaluation, the Company s principal executive and financial officers concluded that the Company s disclosure controls and procedures are effective 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.

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 second ORADUR-opioid, 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 second ORADUR-opioid, Memryte, CHRONOGESIC or other pharmaceutical systems, we will not be able to earn revenue from them, which would materially harm our business.

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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, preclinical (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:

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

TRANSDUR-Sufentanil Patch Our collaborator Endo has commenced its Phase II clinical program for TRANSDUR-Sufentanil for the U.S. and Canadian markets.

ELADUR A Phase IIa clinical trial in PHN in the U.S. has completed enrollment with results anticipated in the fourth quarter of 2007.

Remoxy According to Pain Therapeutics and King, a pivotal Phase III trial is ongoing with Remoxy under an approved Special Protocol Assessment (SPA) with the FDA, and this trial has completed enrollment with top-line results anticipated in the fourth quarter of 2007.

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

Memryte In the second quarter of 2007, Voyager reported that it has observed positive outcome trends among women, but no positive effect among men in its truncated Phase III clinical trial for Memryte.

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.

Failure to obtain product approvals could delay or limit introduction 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 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.

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.

We or our third-party collaborators, as applicable, may also encounter delays or rejections based upon additional government regulation from future legislation, administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. We or our third-party collaborators, as applicable, may encounter similar delays in foreign countries. Sales of our pharmaceutical systems outside the United States are subject to foreign regulatory standards that vary from country to country. The time required to obtain approvals from foreign countries may be shorter or longer than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. We or our third-party collaborators, as applicable, may be unable to obtain requisite approvals from the FDA and foreign regulatory authorities, and even if obtained, such approvals may not be on a timely basis, or they may not cover the clinical uses that we specify. If we or our third-party collaborators, as applicable, fail to obtain timely clearance or approval for our development products, we or they will not be able to market and sell our pharmaceutical systems, which will limit our ability to generate revenue.

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. 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, Remoxy and a second ORADUR-

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opioid, Memryte and CHRONOGESIC. 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, Memryte, Remoxy and a second ORADUR-opioid, 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 long term supply agreement with Corium International, Inc. for clinical and commercial supplies of ELADUR and a long term supply agreement with Hospira Worldwide, Inc. for clinical and commercial supplies of POSIDUR. 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. See We rely heavily on third parties to support development, clinical testing and manufacturing of our pharmaceutical systems and 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. Under our development and commercialization agreement with ALZA, we cannot subcontract the manufacture of subassemblies of the DUROS system components of our DUROS-based pharmaceutical systems to third parties which have not been approved by ALZA.

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.

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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 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 September 30, 2007, had an accumulated deficit of approximately $232.5 million. We expect to continue to incur significant operating losses over the next several years as we continue to incur significant costs for research and development, clinical trials, manufacturing, sales and general and administrative functions. Our ability to achieve profitability depends upon our ability, alone or with others, to successfully complete the development of our proposed pharmaceutical systems, obtain the required regulatory clearances, and manufacture and market our proposed pharmaceutical systems. Development of pharmaceutical systems is costly and requires significant investment. In addition, we may choose to license from third parties either additional drug delivery platform technology or rights to particular drugs or other appropriate technology for use in our pharmaceutical systems. The license fees for these technologies or rights would increase the costs of our pharmaceutical systems.

To date, we have not generated significant revenue from the commercial sale of our pharmaceutical systems and do not expect to do so in the near future. Our current product revenues are from the sale of the ALZET product line and the sale of LACTEL biodegradable polymers, and from payments under collaborative research and development agreements with third parties. We do not expect our product revenues to increase significantly in the near future, and we do not expect that collaborative research and development revenues will exceed our actual operating expenses. We do not anticipate commercialization and marketing of our pharmaceutical systems in development in the near future, and therefore do not expect to generate sufficient revenues to cover expenses or achieve profitability in the near future.

We may 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.

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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.

If we do not generate sufficient cash flow through increased revenues or raising additional capital, we may not be able to meet our substantial debt obligations that become due in 2008

As of September 30, 2007, we had approximately $33.1 million in short-term convertible subordinated notes which mature and are due in June 2008, $150,000 in lease obligations and $675,000 in bonds payable. Our substantial indebtedness, which totaled $34.0 million at September 30, 2007 and $24.4 million at October 31, 2007, has impacted and will continue to impact us by:

- making it more difficult to obtain additional financing;
- requiring interest payments to service the debt; and
- constraining our ability to react quickly in an unfavorable economic climate.

Currently we are not generating positive cash flow and may not have sufficient funds to meet our debt obligations when they become due. If the market price of our common stock on the due date of our notes is below $3.15 per share, the approximate equity conversion price of the notes, it will be highly unlikely that the holders of a large percentage of our outstanding convertible subordinated notes will convert such securities to equity in accordance with their existing terms. As of September 30, 2007, we had cash, cash equivalents and investments of $66.6 million. We expect to use substantially all of these assets to fund our on-going operations over the next few years. We may not generate sufficient cash from operations to repay our convertible subordinated notes or satisfy any other of these debt obligations when they become due and may have to take steps to defer programs and costs, and raise additional financing from the sale of equity or debt securities or otherwise restructure our obligations in order to do so. There can be no assurance that any such financing or restructuring will be available to us on commercially acceptable terms, if at all. If we are unable to satisfy our debt service requirements, substantial liquidity problems could result, and we may be forced to accept a financing or restructure our debt on unfavorable terms, seek strategic alternatives or seek protection under applicable bankruptcy laws. Any of the foregoing could materially impair the value of our common stock.

We may be required to redeem our outstanding convertible subordinated notes before maturity, and we may not have sufficient funds to do so. The redemption rights in our outstanding convertible subordinated notes could discourage a potential acquirer

If a fundamental change occurs, we may be required to redeem all or part of the remaining $23.6 million in outstanding principal as of October 31, 2007, plus any accrued but unpaid interest on our outstanding convertible subordinated notes. A fundamental change is defined as:

- any transaction or event in connection with which all or substantially all of our common stock is exchanged for, converted into, acquired for or constitutes solely the right to receive consideration which is not all or substantially all common stock listed on a United States national securities exchange or approved for quotation on the Nasdaq Global Market or any similar United States system of automated dissemination of quotations of securities prices, or,

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if for any reason, our common stock is no longer listed for trading on a United States national securities exchange nor approved for trading on the Nasdaq Global Market.

If there is a fundamental change, we may not have enough funds to pay the redemption price for all tendered notes. In addition, any credit agreement or other agreements relating to our indebtedness may contain provisions prohibiting redemption of the notes under certain circumstances, or expressly prohibit our redemption of the notes upon a designated event or may provide that a designated event constitutes an event of default under that agreement. Our failure to redeem tendered notes would constitute an event of default under the indenture, which might also constitute a default under the terms of our other indebtedness. Any such default could cause us to seek to restructure our indebtedness or seek protection under applicable bankruptcy laws, either of which could materially impair the value of our common stock.

This redemption feature upon fundamental change could also discourage a potential acquirer. However, this redemption feature is not the result of management s knowledge of any specific effort to obtain control of us by means of a merger, tender offer or solicitation, or part of a plan by management to adopt a series of anti-takeover provisions. The term fundamental change is limited to specified transactions and may not include other events that might adversely affect our financial condition or business operations.

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. Furthermore, unless terminated or amended, commencing May 1, 2008, our agreement with Endo with respect to CHRONOGESIC requires us to pay fifty percent (50%) of the development cost of CHRONOGESIC for the U.S. and Canadian market, which may require us to devote significant funds in excess of what we may otherwise choose to spend on the program. 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 CHRONOGESIC and 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.

In addition to customary termination rights, our agreement with Endo for the development and commercialization of CHRONOGESIC in the United States and Canada can be terminated by Endo in the event that (i) we have not delivered to Endo on or before March 31, 2008 a written notice that a human pharmacokinetic trial had been completed with CHRONOGESIC, together with a full study report of the results of the trial or (ii) Endo, determines, in its sole discretion, to terminate the agreement during the sixty-day period after our delivery of the notice, provided, that, in each case Endo delivers to us its written notice of termination prior to April 30, 2008.

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.

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 CHRONOGESIC and TRANSDUR-Sufentanil in the United States and Canada once such products are 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

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

We may 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 materially harm our business.

We and our third-party collaborators may not sell our pharmaceutical systems effectively

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

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our pharmaceutical systems;
- cease operations with little or no notice to us;

offer, design, manufacture or promote competing product lines;

fail to maintain adequate inventory and thereby restrict use of our pharmaceutical systems; or

build up inventory in excess of demand thereby limiting future purchases of our pharmaceutical systems resulting in significant quarter-to-quarter variability in our sales.

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

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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. See We may not be able to manufacture sufficient quantities of our development products to support our clinical and commercial requirements at an acceptable cost, and we have limited manufacturing experience. 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 second ORADUR-opioid, 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 second ORADUR-opioid 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 October 31, 2007, we held 29 issued U.S. patents and 80 issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have 69 pending U.S. patent applications and have filed 58 patent applications under the Patent Cooperation Treaty, from which 155 national phase applications are currently pending in Europe, Australia, Japan, Canada, Mexico, New Zealand, Brazil, Israel, India, Hong Kong, Eurasia, Republic of Korea, Norway, the Russian Federation, South Africa, Ukraine and China. Our patents expire at various dates starting in the year 2012.

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

proceeds of these infringement actions.

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

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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*) and other cases 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. See 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 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 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

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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 are currently developing require the use of proprietary drugs to which we do not have commercial rights. For example, our research collaboration with the University of Maastricht has demonstrated that the use of a proprietary angiogenic factor in a pharmaceutical system can lead to elevated local concentration of the angiogenic factor in the pericardial sac of the heart, resulting in physical changes, including the growth of new blood vessels. We do not currently have a license to develop or commercialize a pharmaceutical system containing such proprietary angiogenic factor.

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 second ORADUR-opioid, 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. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our pharmaceutical systems containing controlled substances and subject us to enforcement action. In addition, because of their restrictive nature, these regulations could limit our commercialization of our pharmaceutical systems containing controlled substances.

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

We may incur significant non-cash charges related to impairment write-downs of our long-lived assets, including goodwill and other intangible assets.

We will continue to incur non-cash charges related to amortization of other intangible assets. 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

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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 2006 and determined that goodwill was not impaired as of December 31, 2006. 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 will also adversely impact or delay our profitability.

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. Although we have obtained key man life insurance policies for each of Messrs. Theeuwes and Brown in the amount of $1.0 million, this insurance may not adequately compensate us for the loss of their services. 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.

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 and development efforts, could be destroyed.

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Risks Related To Our Industry

The market for our pharmaceutical systems is new, 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, 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, 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.

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

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pricing and reimbursement policies of government and third-party payors such as insurance companies, health maintenance organizations, hospital formularies and other health plan administrators.

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

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

The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and third-party collaborators and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care, and the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

The successful commercialization of our pharmaceutical systems will depend in part on the extent to which appropriate reimbursement levels for the cost of our pharmaceutical systems and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payors are increasingly limiting payments or reimbursement for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may limit reimbursement or payment for our products. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could materially harm our ability to operate profitably.

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

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

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

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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 these outstanding options are ultimately exercised, there will be dilution to investors. In addition, conversion of some or all of the $23.6 million aggregate principal amount as of October 31, 2007 of Notes that we issued in June and July 2003 will dilute the ownership interests of investors. Investors may experience further dilution of their investment if we raise capital through the sale of additional equity securities or debt securities or grant additional stock options to employees and consultants. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices for our common stock.

We may choose to purchase a portion of our convertible subordinated notes in exchange for shares of our common stock or pay note holders to convert out notes. These transactions could dilute existing stockholders, increase the volatility of our stock and consume our existing cash

To the extent we are able to do so on terms favorable to us, we may choose to purchase a portion of our outstanding Notes due June 2008 from time to time in privately negotiated transactions under Section 3(a)(9) of the Securities Act of 1933. In the third quarter of 2005, we exchanged approximately $2.7 million in principal amount of our 6.25% convertible subordinated notes with our note holders for approximately 911,730 shares of our common stock. In May 2006, we entered into an agreement with the holder of such notes with an aggregate principal amount of $20.0 million to convert such notes into an aggregate of 6,349,206 shares of common stock, as originally set forth in the indenture for such Notes, and pursuant to which we made a cash payment to such holder of $2.9 million. In September 2007, we entered into an agreement with the holders of such notes with an aggregate principal amount of $4.2 million to convert such notes into an aggregate of 1,330,793 shares of common stock, as originally set forth in the indenture for such Notes, and pursuant to which we made a cash payment to such holders of $293,440. In October 2007, we entered into an agreement with the holders of such notes with an aggregate principal amount of $9.5 million to convert such notes into an aggregate of 3,030,472 shares of common stock, as originally set forth in the indenture for such Notes, and pursuant to which we made a cash payment to such holders of $688,450. The issuance of shares of our common stock in such transactions will dilute our existing investors. To the extent such shares are resold, such transactions may increase the volatility of our stock. Such transactions also consume our cash in a manner that may not benefit our stockholders.

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 sublicensee 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 second ORADUR-opioid, Memryte, CHRONOGESIC or other pharmaceutical systems;
- announcements of FDA non-approval of our pharmaceutical systems, or delays in the FDA or other foreign regulatory agency review process;
- adverse actions taken by regulatory agencies with respect to our pharmaceutical systems or our or our third-party collaborator s clinical trials, manufacturing processes or sales and 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;

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sales of our common stock by our executive officers, directors and five percent stockholders or sales of substantial amounts of common stock;

changes in accounting principles; and

loss of any of our key scientific or management personnel.

Pursuant to a Purchase Agreement with Morgan Stanley & Co., Incorporated, we filed a registration statement on August 29, 2003 with the SEC on Form S-3 to register an aggregate of $60.0 million in convertible subordinated notes and the shares of common stock issuable upon conversion of the notes for resale. The registration statement was declared effective by the SEC on November 3, 2003. The balance as of October 31, 2007 of our convertible subordinated notes consisting of $23.6 million in outstanding principal, are convertible into shares of our common stock at a conversion rate of 317.4603 shares per $1,000 principal amount of notes, subject to adjustment and will bear interest at a rate of 6.25% per annum. So long as this registration is effective, shares covered thereunder are tradable without limitation. If substantial amounts of our common stock issued upon conversion of our promissory notes or otherwise were to be sold in the public market, the market price of our common stock could fall. In addition, the existence of our convertible subordinated notes may encourage short selling by market participants. 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.

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.

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ITEM 2. ***Unregistered Sales of Equity Securities and Use of Proceeds***
None

ITEM 3. ***Defaults Upon Senior Securities***
None

ITEM 4. ***Submission of Matters to a Vote of Security Holders***
None

ITEM 5. ***Other Information***
None

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ITEM 6. Exhibits

(a) Exhibits:

31.1	Rule 13a-14(a) Section 302 Certification of James E. Brown.
31.2	Rule 13a-14(a) Section 302 Certification of Matthew J. Hogan.
32.1	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of James E. Brown.
32.2	Certificate pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of Matthew J. Hogan.

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SIGNATURES

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

DURECT CORPORATION

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

Date: November 8, 2007

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

Date: November 8, 2007