DURECT CORP
Form 10-Q
May 10, 2006
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2006

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 April 28, 2006, there were 62,095,918 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)

	March 31, 2006 (unaudited)	December 31, 2005 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,093	$ 65,542
Short-term investments	29,731	18,022
Restricted investments	203	321
Accounts receivable, net of allowances of $110 and $128, respectively	3,164	4,488
Inventories	1,998	2,047
Prepaid expenses and other current assets	2,016	3,659
Total current assets	81,205	94,079
Property and equipment, net	7,580	7,304
Goodwill	6,399	6,399
Intangible assets, net	235	536
Long-term investments	12,330	5,459
Restricted investments	1,505	1,653
Other long-term assets	1,825	1,984
Total assets	$ 111,079	$ 117,414
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,029	$ 1,835
Accrued liabilities	3,107	3,874
Contract research liability	661	1,418
Interest payable on convertible notes	1,045	149
Deferred revenue, current portion	2,272	2,367
Equipment financing obligations and term loan, current portion	21	34
Bonds payable, current portion	200	200
Total current liabilities	8,335	9,877
Equipment financing obligations and term loan, noncurrent portion	129	27
Bonds payable, noncurrent portion	675	675
Convertible subordinated notes	57,337	57,337
Deferred revenue, noncurrent portion	5,469	6,016
Other long-term liabilities	180	130
Commitments		
Stockholders equity:		
Common stock, $0.0001 par value: 110,000 shares authorized at March 31, 2006 and December 31, 2005 respectively; 62,000 and 61,609 shares issued and outstanding at March 31, 2006 and December 31, 2005, respectively	6	6

Additional paid-in capital	240,874	239,057
Deferred royalties and commercial rights	(13,480)	(13,480)
Accumulated other comprehensive loss	(169)	(212)
Accumulated deficit	(188,277)	(182,019)
Stockholders equity	38,954	43,352
Total liabilities and stockholders equity	$ 111,079	$ 117,414

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 March 31,	
	2006	**2005**
Collaborative research and development and other revenue	$ 3,058	$ 3,597
Product revenue, net	2,153	1,757
Total revenues	5,211	5,354
Operating expenses:		
Cost of revenues (1)	829	671
Research and development (1)	7,164	6,664
Selling, general and administrative (1)	3,005	2,508
Amortization of intangible assets	300	303
Total operating expenses	11,298	10,146
Loss from operations	(6,087)	(4,792)
Other income (expense):		
Interest and other income	906	485
Interest expense	(1,077)	(1,120)
Net other income (expense)	(171)	(635)
Net loss	$ (6,258)	$ (5,427)
Net loss per common share, basic and diluted	$ (0.10)	$ (0.10)
Shares used in computing basic and diluted net loss per share	61,837	51,887

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

Cost of revenues	$ 8	$
Research and development	614	46
Selling, general and administrative	321	4
Total stock-based compensation	$ 943	$ 50

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)

	Three months ended March 31,	
	2006	**2005**
Cash flows from operating activities		
Net loss	$ (6,258)	$ (5,427)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	511	576
Amortization	300	303
Noncash charges related to stock-based compensation	943	50
Changes in assets and liabilities:		
Accounts receivable	1,324	(11,477)
Inventories	73	23
Prepaid expenses and other assets	1,802	104
Accounts payable	(806)	(360)
Accrued liabilities and other long-term liabilities	(716)	(293)
Contract research liability	(757)	512
Interest payable on convertible notes	896	937
Deferred revenue	(642)	9,806
Total adjustments	2,928	181
Net cash and cash equivalents used in operating activities	(3,330)	(5,246)
Cash flows from investing activities		
Purchases of property and equipment	(633)	(677)
Purchases of available for sale securities	(28,185)	(3,689)
Proceeds from maturities of available for sale securities	9,913	8,041
Net cash and cash equivalents provided by (used in) investing activities	(18,905)	3,675
Cash flows from financing activities		
Payments on term loan and equipment financing obligations	(64)	(74)
Net proceeds from issuances of common stock through exercise of options	850	85
Net cash and cash equivalents provided by financing activities	786	11
Net decrease in cash and cash equivalents	(21,449)	(1,560)
Cash and cash equivalents, beginning of the period	65,542	20,032
Cash and cash equivalents, end of the period	$ 44,093	$ 18,472

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 and Basis of Presentation

DURECT Corporation (the Company) was incorporated in the state of Delaware on February 6, 1998. The Company is a pharmaceutical company developing pharmaceutical therapies based on its proprietary drug formulations and delivery platform technologies. The Company has several products under development by itself and with third party collaborators in the areas of pain and other chronic and episodic diseases and disorders. The Company also conducts research and development of pharmaceutical products in collaboration with third party pharmaceutical and biotechnology companies.

In addition to its core business, 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. Until December 31, 2004, the polymer business was conducted by the Company s wholly owned subsidiary, Absorbable Polymers International Corporation (API), formerly known as Birmingham Polymers Inc., an Alabama corporation. API was merged with and into DURECT on December 31, 2004.

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, 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 accounting principles generally accepted in the United States. The unaudited financial statements reflect all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair presentation of the financial position at March 31, 2006, the operating results for the three months ended March 31, 2006 and 2005, and cash flows for the three months ended March 31, 2006 and 2005. The condensed balance sheet as of December 31, 2005 has been derived from audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States 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 Securities and Exchange Commission.

As discussed later in this Note 1, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123(R), *Share-Based Payment,* on January 1, 2006 using the modified prospective transition method. Accordingly, the Company s loss from operations for the three months ended March 31, 2006 includes approximately $943,000 in stock-based employee compensation expense for stock options and the Company s employee stock purchase plan. Because the Company elected to use the modified prospective transition method, results for prior periods have not been restated.

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

Reclassifications

Certain prior period amounts related to stock-based compensation expense in the statements of operations 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):

	March 31, 2006 (unaudited)	December 31, 2005
Raw materials	$ 225	$ 203
Work in process	709	493
Finished goods	1,064	1,351
Total inventories	$ 1,998	$ 2,047

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Stock-Based Compensation

At March 31, 2006, the Company has six stock-based employee compensation plans, which are described more fully in Note 4. Prior to January 1, 2006, the Company accounted for stock-based employee compensation plans under the recognition and measurement provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees,* and related Interpretations, as permitted by FASB Statement (SFAS) 123, *Accounting for Stock-Based Compensation.* Accordingly, no stock-based employee compensation cost was recognized in the Statement of Operations for options granted under the Company s stock-based employee compensation plans during the three months ended March 31, 2005 as all options granted under those plans had exercise prices equal to the fair market value of the Company s common stock on the date of grant. The Company also recorded no compensation cost in this period in connection with the Company s employee stock purchase plan as the purchase price of the stock was not less than 85% of the lower of the fair market value of the Company s common stock at the beginning of each offering period or at the end of each purchase period. In accordance with SFAS 123 and SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure,* the Company provided pro forma net loss and net loss per share disclosures for each period prior to the adoption of SFAS 123(R) as if the Company had applied the fair value-based method in measuring compensation cost for the Company s stock-based compensation plans.

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 months ended March 31, 2006 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 Securities and Exchange Commission 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).

As a result of adopting SFAS 123(R) on January 1, 2006, the Company s net loss for the three months ended March 31, 2006 is $943,000 higher than if it had continued to account for stock-based compensation under APB No. 25. Basic and diluted net loss per share for the three months ended March 31, 2006 would have been ($0.09) if the Company had not adopted SFAS No. 123(R), compared to reported basic and diluted net loss per share of ($0.10). The adoption of SFAS 123(R) had no impact on cash flows from operations or financing.

The following table illustrates the effect on the Company s net loss and net loss per share for the three months ended March 31, 2005 if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based compensation using the Black-Scholes valuation model (in thousands) in that period.

	Three months ended March 31, 2005
Net loss as reported in prior year (1)	$ (5,427)
Add: Stock-based employee compensation expense included in reported net loss	2
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards (2)	(988)
Net loss, including stock-based employee compensation expense (3)	$ (6,413)
Net loss per share:	
Basic and diluted as reported	$ (0.10)
Basic and diluted pro forma	$ (0.12)

1) Net loss and net loss per share as reported for periods prior to January 1, 2006 did not include stock-based compensation expense for employee stock options and our employee stock purchase plan because the Company had not adopted the recognition provisions of SFAS 123.

2) Stock-based compensation expense for periods prior to January 1, 2006 was calculated based on the pro forma application of SFAS 123.
3) Net loss and net loss per share including stock-based employee compensation for periods prior to January 1, 2006 are based on the pro forma application of SFAS 123.

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.

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Revenue from the sale of intellectual property rights is recognized upon assignment of such rights by the Company to a third party, provided the collectibility is assured and the Company has no future performance obligations related to such rights, except for the on-going de minimus assistance the Company would provide to the third party with respect to the maintenance of such rights.

Upfront payments received upon execution of collaborative agreements are recorded as deferred revenue and recognized as collaborative research and development revenue 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 corporate partners is recognized as the related research and development services are performed. These research payments received under each respective agreement are not refundable and are generally based on reimbursement of qualified expenses, as defined in the agreements. Research and development expenses under the collaborative research and development agreements generally approximate or exceed the revenue recognized under such agreements over the term of the respective agreements. Deferred revenue may result when we do 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 March 31,	
	2006	2005
Partner		
Endo Pharmaceuticals, Inc. (1)	$ 790	$ 1,086
Pain Therapeutics, Inc.	1,822	1,194
Voyager Pharmaceutical Corporation	299	1,004
Others	147	313
Total collaborative research and development revenue	$ 3,058	$ 3,597

Notes:

1. Amounts related to up-front fees were $547,000 and $155,000 for the three months ended March 31, 2006 and 2005, respectively. The amount included in the first quarter of 2005 represented the amount recognized over the period from March 10, 2005 to March 31, 2005 since the license agreement with Endo relating to TRANSDUR-Sufentanil was executed on March 10, 2005.

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. 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 collaboration partner. 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 only to 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 the related services are performed, generally ratably over the period of service. Purchased research and development is recognized in purchase business combinations for the portion of the purchase price allocated to the appraised value of in-process technologies. The portion assigned to in-process technologies excludes the value of core and developed technologies, which are recorded as intangible assets.

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The research and development expenses associated with the Company s major development products approximate the following (in thousands):

	Three months ended March 31,	
	2006	2005
SABER-Bupivacaine	$ 2,055	$ 1,302
TRANSDUR-Sufentanil	324	2,361
Remoxy	1,389	906
Memryte	244	1,052
CHRONOGESIC	470	392
Others	2,682	651
Total research and development expenses	$ 7,164	$ 6,664

Comprehensive Loss

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

	Three Months Ended March 31,	
	2006	2005
Net loss	$ (6,258)	$ (5,427)
Net change in unrealized gain (loss) on available for sale investments	43	(102)
Comprehensive loss	$ (6,215)	$ (5,529)

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding, less the weighted average number of common shares subject to repurchase or held in escrow pursuant to an acquisition agreement, 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.

The computation of diluted net loss per share for the three months ended March 31, 2006 excludes the impact of options to purchase 9.2 million shares of common stock and 18.2 million shares of common stock issuable upon conversion of the subordinated notes at March 31, 2006, as inclusion of such shares would be antidilutive in that period.

The computation of diluted net loss per share for the three months ended March 31, 2005 excludes the impact of options to purchase 8.7 million shares of common stock, warrants to purchase 770 shares of common stock, and 19.0 million shares of common stock issuable upon conversion of the subordinated notes at March 31, 2005, as inclusion of such shares would be antidilutive in that period.

Operating Leases

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

condensed statements of operations.

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Note 2. Agreement with Endo Pharmaceuticals

Agreements with Endo Pharmaceuticals, Inc. (Endo)

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

Pursuant to the agreement, Endo was obligated to pay an upfront, nonrefundable fee of $10 million. In April 2005, Endo paid the Company the $10 million upfront fee. Endo is also obligated to pay to the Company additional payments of up to approximately $35 million in the aggregate if predetermined regulatory and commercial milestones are achieved. In addition, Endo reimburses the Company for all qualified research and development expenses incurred for TRANSDUR-Sufentanil. If commercialized, Endo will also pay the Company product royalties based on the net sales of TRANSDUR-Sufentanil under the agreement. The Company has the right to co-promote TRANSDUR-Sufentanil under terms specified in the agreement. The agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties and indemnities. The agreement shall continue in effect until terminated. The agreement provides each party with specified termination rights, including the right of each party to terminate the agreement upon material breach of the agreement by the other party. In addition, Endo shall have the right to terminate the agreement at any time without cause subject to a specified notice period and due to adverse product events, legal impediment or the issuance of a final, non-appealable court order enjoining Endo from selling TRANSDUR-Sufentanil in the U.S. and Canada as a result of an action for patent infringement by a third party, provided that in the latter instance, the Company will be required to pay Endo a termination fee ranging from $5 million to $10 million, depending on the date of termination.

The $10 million up-front fee is recognized as revenue ratably over the term of the Company s continuing involvement with Endo with respect to TRANSDUR-Sufentanil. The term of the continuing involvement has been estimated based on the

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current Product Development Plan pursuant to the agreement. For the three months ended March 31, 2006 and 2005, the Company recognized $547,000 and $155,000 in collaborative research and development revenue related to this upfront fee. Research and development expenses associated with TRANSDUR-Sufentanil in the three months ended March 31, 2006 and 2005 reimbursable by Endo under the license agreement were recognized as collaborative research and development revenue in the three months ended March 31, 2006 and 2005. Total collaborative research and development revenue under this arrangement was $790,000 and $1.1 million in the three months ended March 31, 2006 and 2005, respectively.

CHRONOGESIC

In November 2002, the Company entered into a development, commercialization and supply license agreement with 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, in November 2004 and again in January 2006 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, 2007. Commencing on May 1, 2007, 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 its 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 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. Based on the Company s projected financial performance of the product in the U.S. and Canada, the Company anticipates that our share of such profits, if CHRONOGESIC is commercialized, will be approximately 50%. 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, 2007 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, 2007.

The Company has not recognized any collaborative research and development revenue with respect to Chronogesic under this agreement and its amendments.

Agreement with Pain Therapeutics, Inc. (Pain Therapeutics)

In December 2002, the Company entered into an exclusive agreement with Pain Therapeutics to develop and commercialize on a worldwide basis Remoxy and other oral sustained release, abuse deterrent opioid products incorporating four specified opioid drugs, using the ORADUR technology. The agreement also provides Pain Therapeutics with the exclusive right to commercialize products developed under the agreement on a worldwide basis. In connection with the execution of the agreement, Pain Therapeutics paid the Company upfront fees of $900,000 in December 2002 and $100,000 in October 2003. In December 2005, the Company amended its agreement with Pain Therapeutics in order to specify its obligations with respect to the supply of key excipients for use in the licensed products. Under the agreement, as amended, the Company is responsible for formulation development, supply of selected key excipients used in the manufacture of licensed products and other specified tasks. The Company will receive additional payments if certain development and regulatory milestones are achieved. In addition, if commercialized, the Company will receive royalties for Remoxy and other licensed products which do not contain an opioid antagonist of between 6.0% to 11.5% of net sales of the product depending on sales volume. This agreement can be terminated by either party for material breach by the other party and by Pain Therapeutics without cause. Under the agreement, Pain Therapeutics reimburses the Company qualified expenses incurred by the Company in connection with the development program. The Company recognizes collaborative research and development revenue related to research and development activities for Remoxy and other development programs based on reimbursement of qualified expenses as defined in the collaborative agreement and related amendment with Pain Therapeutics. Total collaborative research and development revenue recognized under the agreements with Pain Therapeutics was $1.8 million and $1.2 million in the three months ended March 31, 2006 and 2005, respectively.

Agreement with Voyager Pharmaceutical Corporation (Voyager)

In July 2002, the Company entered into a development and commercialization agreement with 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 and by Voyager without cause. Under the agreement, Voyager reimburses to the Company qualified expenses incurred by the Company in connection with the development program for Memryte. The Company recognizes collaborative research and development revenue related to research and development activities for Memryte based on reimbursement of qualified expenses as defined in the collaborative agreement with Voyager. Total collaborative research and development revenue recognized under the agreement with Voyager was $299,000 and $1.0 million in the three months ended March 31, 2006 and 2005, respectively.

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Note 3. Goodwill and Intangible Assets

Intangible assets consist of the following (in thousands):

	March 31, 2006		
	Gross Intangibles	Accumulated Amortization	Net Intangibles
Developed technology	$ 3,600	$ (3,462)	$ 138
Patents	466	(402)	64
Other intangibles	3,260	(3,227)	33
Total	$ 7,326	$ (7,091)	$ 235

	December 31, 2005		
	Gross Intangibles	Accumulated Amortization	Net Intangibles
Developed technology	$ 3,600	$ (3,302)	$ 298
Patents	466	(384)	82
Other intangibles	3,260	(3,104)	156
Total	$ 7,326	$ (6,790)	$ 536

The Company expects to amortize the remaining net intangible assets balance of $235,000 as follows: $123,000 in the nine months ending December 31, 2006, $31,000 in each of the years 2007, 2008, and 2009, and $19,000 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 March 31, 2006 and December 31, 2005. In the fourth quarter of 2005, 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 March 31, 2006, the Company has six stock-based employee compensation plans, which are described below. The employee stock-based compensation cost that has been included in the condensed statements of operations was $943,000 for the three month ended March 31, 2006. Stock-based compensation cost capitalized as part of inventory for the three months ended March 31, 2006 was $25,000.

Description of Stock-Based Compensation Plans

1998 Stock Option Plan (Incentive Stock Plan)

In March 1998, the Company adopted the DURECT Corporation 1998 Stock Option Plan under which incentive stock options and non-statutory stock options may be granted to employees, directors of, or consultants to, the Company and its affiliates.

Options granted under the 1998 Stock Option Plan expire no later than ten years from the date of grant. Options may be granted with different vesting terms from time to time not to exceed five years from the date of grant.

The option price of an incentive stock option granted to an employee or of a nonstatutory stock option granted to any person who owns stock representing more than 10% of the total combined voting power of all classes of stock of the Company (or any parent or subsidiary) shall be no less than 110% of the fair market value per share on the date of grant. The option price of an incentive stock option granted to any other employee shall be no less than 100% of the fair market value per share on the date of grant. The option price of a nonstatutory stock option that

is granted to any other person shall be no less than 85% of the fair market value per share on the date of grant.

In January 2000, the Company ceased granting options from 1998 Stock Option Plan. As of March 31, 2006, options to purchase 19,000 shares of common stock were outstanding under the 1998 Stock Option Plan.

2000 Stock Plan (Incentive Stock Plan)

In January 2000, the Company s Board of Directors and stockholders adopted the DURECT Corporation 2000 Stock Plan, under which incentive stock options and non-statutory stock options and stock purchase rights may be granted to employees, consultants and non-employee directors. The 2000 Stock Plan was amended by written consent of the Board of Directors in March 2000 and written consent of the stockholders in August 2000.

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In April 2005, the Board of Directors approved certain amendments to the 2000 Stock Plan. At the Company s annual shareholders meeting in June 2005, the shareholders approved the amendments of the 2000 Stock Plan to: (i) expand the types of awards that the Company may grant to eligible service providers under the Stock Plan to include restricted stock units, stock appreciation rights and other similar types of awards (including other awards under which recipients are not required to pay any purchase or exercise price) as well as cash awards; and (ii) include certain performance criteria that may be applied to awards granted under the Stock Plan. A total of 15,296,500 shares of common stock have been reserved for issuance under this plan.

Options granted under the 2000 Stock Plan expire no later than ten years from the date of grant. Options may be granted with different vesting terms from time to time not to exceed five years from the date of grant.

The option price of an incentive stock option granted to an employee or of a nonstatutory stock option granted to any person who owns stock representing more than 10% of the total combined voting power of all classes of stock of the Company (or any parent or subsidiary) shall be no less than 110% of the fair market value per share on the date of grant. The option price of an incentive stock option granted to any other employee shall be no less than 100% of the fair market value per share on the date of grant.

As of March 31, 2006, 5,252,951 shares of common stock were available for future grant and options to purchase 8,612,005 shares of common stock were outstanding under the 2000 Stock Plan.

2000 Directors Stock Option Plan

In March 2000, the Board of Directors adopted the 2000 Directors Stock Option Plan. A total of 300,000 shares of common stock had been reserved initially for issuance under this plan. The directors plan provides that each person who becomes a non-employee director of the Company after the effective date of this offering will be granted a non-statutory stock option to purchase 20,000 shares of common stock on the date on which the optionee first becomes a non-employee director of the Company. This plan also provides that each option granted to a new director shall vest at the rate of 33 1/3% per year and each annual option of 5,000 shares shall vest in full at the end of one year.

At the Company s annual shareholders meeting in June 2002, the shareholders approved an amendment of the 2000 Directors Stock Option Plan to: (i) increase the number of stock options granted to a non-employee director on the date which such person first becomes a director from 20,000 to 30,000 shares of common stock; (ii) increase the number of stock options granted to each non-employee director on the date of each annual meeting of the stockholders after which the director remains on the Board from 5,000 to 12,000 shares of common stock; and (iii) reserve 200,000 additional shares of common stock for issuance under the Directors Stock Option Plan so that the total number of shares reserved for issuance is 500,000.

In April 2005, the Board of Directors approved certain amendments to the 2000 Directors Stock Option Plan. At the Company s annual shareholders meeting in June 2005, the shareholders approved the amendments of the 2000 Directors Stock Option Plan to: (i) increase the number of shares of common stock issuable under the Director s Plan by an additional 425,000 shares, to an aggregate of 925,000 shares; (ii) increase the number of option shares issued to nonemployee directors annually in connection with their continued service on the Board (from 12,000 shares) to 20,000 shares; and (iii) modify the vesting of such annual option grants so that such shares vest completely on the day before the first anniversary of the date of grant.

As of March 31, 2006, 684,000 shares of common stock were available for future grant and options to purchase 199,000 shares of common stock were outstanding under the 2000 Director s Stock Option Plan.

1993 Stock Option Plan of Southern BioSystems, Inc.

In April 2001, the Company assumed the 1993 Stock Option Plan of Southern BioSystems, Inc. (1993 SBS Plan) in connection with its acquisition of SBS. Pursuant to the 1993 SBS Plan, incentive stock options may be granted to employees, and nonstatutory stock options may be granted to employees, directors, and consultants, of the Company and its affiliates. A total of 662,191 shares of common stock have been reserved for issuance under this plan. Options granted under the 1993 SBS Plan expire no later than ten years from the date of grant. Options may be granted with different vesting terms from time to time not to exceed five years from the date of grant. As of March 31, 2006, there were no shares of common stock available for future grant and options to purchase 216,310 shares of common stock were outstanding under the 1993 SBS Plan.

1995 Nonqualified Stock Option Plan of Southern Research Technologies, Inc.

In April 2001, the Company also assumed the 1995 Nonqualified Stock Option Plan of Southern Research Technologies, Inc. (1995 SRT Plan) in connection with its acquisition of SBS. Under this plan, non-statutory stock options

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may be granted to employees, directors, and consultants, of the Company and its affiliates. A total of 243,609 shares of common stock have been reserved for issuance under this plan. Options granted under the 1995 SRT Plan expire no later than ten years from the date of grant. Options may be granted with different vesting terms from time to time but not to exceed five years from the date of grant. As of March 31, 2006, there were no shares of common stock available for future grant or outstanding options under the 1995 SRT Plan.

2000 Employee Stock Purchase Plan

In August 2000, the Company adopted the 2000 Employee Stock Purchase Plan. This purchase plan will be implemented by a series of overlapping offering periods of approximately 24 months duration, with new offering periods, other than the first offering period, beginning on May 1 and November 1 of each year and ending April 30 and October 31, respectively, two years later. The purchase plan allows eligible employees to purchase common stock through payroll deductions at a price equal to the lower of 85% of the fair market value of the Company s common stock at the beginning of each offering period or at the end of each purchase period. The initial offering period commenced on the effectiveness of the Company s initial public offering. A total of 1,050,000 shares of common stock have been reserved for issuance under this plan. As of March 31, 2006, 541,706 shares of common stock were available for future grant and 508,294 shares of common stock have been issued under the employee stock purchase plan.

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 months ended March 31, 2006 (in thousands).

	Three months ended March 31, 2006
Cost of revenue	$ 8
Research and development	614
Selling, general and administrative	321
	$ 943

As of March 31, 2006, $25,000 of stock-based compensation cost was capitalized in inventory on the balance sheet.

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 months ended March 31, 2006 and 2005:

	Stock Options Three months ended March 31,		Employee Stock Purchase Plan Three months ended March 31,	
	2006	2005	2006	2005
Risk-free rate	4.33-4.83%	3.80-4.18%	4.25-4.42%	2.41%
Expected dividend yield				
Expected life of option (in years)	6.25	3.5	1.25	1.25
Volatility	93-94%	96-102%	53-89%	100%

Stock Option Activity

A summary of stock option activity under all stock-based compensation plans during the three months ended March 31, 2006 is as follows:

Options	Number of Shares	Weighted Average Exercise Price
Outstanding at January 1, 2006	7,571,146	$ 3.92
Options granted	2,329,405	$ 5.26
Options exercised	(390,671)	$ 2.17
Options forfeited	(324,065)	$ 2.74
Options expired	(139,500)	$ 10.12
Outstanding at March 31, 2006	9,046,315	$ 4.29
Exercisable at March 31, 2006	3,797,269	$ 4.79

The weighted average remaining contractual life for options outstanding and exercisable at March 31, 2006 was 7.89 and 6.55 years, respectively. The aggregate intrinsic value of options exercised during the three months ended March 31, 2006 was $989,000. The aggregate intrinsic value of options outstanding and exercisable at March 31, 2006 was $22.6 million and $9.8 million, respectively. The total fair value of options vested during the three months of March 31, 2006 was $1.5 million.

All employee stock options under the Company s stock compensation plans were granted with exercise prices equal to the fair market value of the Company s common stock on the date of grant during the three months ended March 31, 2006 and 2005. The estimated weighted average fair value of the stock options granted during the three months ended March 31, 2006 and 2005 was $4.15 and $2.00 per share, respectively.

There were no shares granted under our employee stock purchase plan during the three months ended March 31, 2006 and 2005. Included in the condensed statement of operations for the three months ended March 31, 2006 is $48,000 in stock-based compensation expense related to the amortization of expenses related to shares previously granted under the Company s employee stock purchase plan.

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As of March 31, 2006, $7.6 million of total unrecognized compensation costs related to nonvested awards is expected to be recognized over a weighted average period of 3.3 years.

The following table summarizes information about stock options outstanding at March 31, 2006:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number of Options Outstanding	Weighted Average Remaining Contractual Life (In years)	Weighted Average Exercise Price	Number of Options Exercisable	Weighted Average Exercise Price
$ 0.35 1.45	216,316	5.12	$ 1.25	133,941	$ 1.17
$ 1.48 1.58	1,219,174	6.94	$ 1.58	701,588	$ 1.58
$ 1.75 2.48	101,600	7.64	$ 2.11	71,475	$ 2.08
$ 2.49 2.51	994,550	7.91	$ 2.51	502,526	$ 2.51
$ 2.57 3.12	591,576	7.06	$ 2.98	335,985	$ 2.97
$ 3.15 3.20	1,248,921	8.72	$ 3.20	323,096	$ 3.20
$ 3.22 4.09	917,870	7.79	$ 3.42	429,870	$ 3.43
$ 4.40 5.26	227,700	9.61	$ 4.88	3,000	$ 5.17
$ 5.27 5.27	2,120,995	9.77	$ 5.27	0	$ 0.00
$ 5.36 13.56	1,407,613	5.70	$ 9.02	1,295,788	$ 9.25
$ 0.35 13.56	9,046,315	7.89	$ 4.29	3,797,269	$ 4.79

The Company received $850,000 in cash from option exercises under all stock-based compensation plans for the three months ended March 31, 2006.

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

This Management s Discussion and Analysis of Financial Condition and Results of Operations for the three months ended March 31, 2006 and 2005 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.*

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 can achieve what drugs or devices alone cannot. Our pharmaceutical systems enable optimized therapy for a given disease or patient population by controlling the rate and duration of drug administration and providing sustained drug delivery.

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

SABER -Bupivacaine

Our post-operative pain relief depot (SABER-Bupivacaine) is a sustained release injectable using our SABER delivery system to deliver bupivacaine, an off-patent anesthetic agent. SABER is a patented controlled drug delivery technology that can be formulated for systemic or local administration of drugs via the parenteral (i.e., injectable) route. SABER-Bupivacaine is designed to be administered around a surgical site after surgery for post-operative pain relief and is intended to provide local analgesia for 3 days or more, which we believe coincides with the time period of the greatest need for post surgical pain control in most patients. SABER-Bupivacaine is currently in Phase II clinical trials. In January 2006, the U.S. Investigational New Drug (IND) application for SABER-Bupivacaine was accepted by the U.S. Food and Drug Administration (FDA).

In April 2006, we announced the results from the Phase II Australian clinical study in hernia patients. The Phase II trial was a dose escalation trial conducted in three cohorts, where three doses, low (Cohort 1), intermediate (Cohort 2) and high (Cohort 3), of SABER-Bupivacaine were evaluated following repair of inguinal hernia. In Cohorts 1, 2 and 3, a total of 6, 15 and 60 patients were enrolled, respectively. Cohorts 2 and 3 included control groups of 5 and 15 patients, respectively, who received commercial bupivacaine as a comparator. Prior to dose escalation, safety and an acceptable pharmacokinetic profile were established. The primary end points of the study were safety and pharmacokinetics. The study also assessed a variety of other secondary endpoints including, among others, pain intensity, pain relief and supplemental analgesic medication usage. Although the study was not designed as an efficacy study to provide statistical conclusions on such secondary endpoints, results from these evaluations are intended to guide the design of future Phase II and Phase III clinical studies.

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

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The results to date from the study are as follows:

All primary end-points of the study were achieved:

Safety Good safety was observed across all Cohorts, with no clinically significant drug related adverse events observed with 61 patients exposed to SABER-Bupivacaine. SABER-Bupivacaine injections also appeared to be well tolerated by patients.

Pharmacokinetics Evaluation of plasma bupivacaine concentrations showed that, across all Cohorts, SABER-Bupivacaine achieved:

sustained plasma concentrations of bupivacaine as measured up to 72 hours

no evidence of burst or spike in plasma concentrations of bupivacaine upon injection

dose linear pharmacokinetics of bupivacaine

Secondary End-points (in Cohort 2 and Cohort 3 with comparator controls groups):

In Cohort 2 (n=15), the patients who were administered SABER-Bupivacaine showed better pain relief, lower pain intensity and reduced supplemental analgesic usage compared with the patients using commercial bupivacaine as measured during the first 4 days after treatment.

In Cohort 3 (n=60), no significant difference was observed in pain relief, pain intensity and supplemental analgesic usage between the patients who were administered SABER-Bupivacaine compared with the patients using commercial bupivacaine as measured during the first 4 days after treatment.

In April 2006, we also initiated dosing in the first U.S. clinical trial, a Phase II, placebo-controlled trial in hernia patients. During the remainder of this year, we intend to initiate several Phase II trials in the U.S. and in other countries in a variety of soft-tissue and orthopedic surgery models for the purpose of selecting the optimal dose and the pain models to be used for our pivotal trials. Pending the successful completion of these Phase II trials and approval of regulatory authorities, we will continue into Phase III trials.

TRANSDUR -Sufentanil

Our transdermal sufentanil patch (TRANSDUR-Sufentanil) uses our proprietary TRANSDUR delivery system to deliver sufentanil, an opioid medication. TRANSDUR-Sufentanil is designed to provide extended chronic pain relief for up to seven days, as compared to the three days of relief provided with currently available opiate patches. We anticipate that the small size of our sufentanil patch (potentially as small as $1/5^{th}$ the size of currently marketed transdermal fentanyl patches for a therapeutically equivalent dose) may offer improved convenience and compliance for patients. In March 2005, we entered into an agreement with Endo Pharmaceuticals granting Endo exclusive rights to develop, market and commercialize TRANSDUR-Sufentanil in the U.S. and Canada. TRANSDUR-Sufentanil is currently in Phase II clinical trials.

Remoxy

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. Remoxy is currently in Phase III trials. In February 2006, Pain Therapeutics and its commercialization 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, under the terms of the SPA for Remoxy, one pivotal Phase III trial is required to file a New Drug Application. The randomized, double-blinded, placebo-controlled, multi-center pivotal trial will enroll 400 patients with moderate-to-severe osteoarthritic pain in multiple U.S. clinical sites. Following a titration period, patients will be randomized to either Remoxy (10-80 mg daily) or placebo for 12 weeks. The primary endpoint is reduction in pain scores over three months compared to baseline. In May 2006, Pain Therapeutics reported that during the first quarter of 2006, it commenced a pivotal Phase III program with Remoxy.

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Memryte

In July 2002, we entered into a development and commercialization agreement with Voyager under which we granted Voyager the exclusive, worldwide right to develop and commercialize a product using the DURIN implant system to deliver the peptide leuprolide acetate to treat Alzheimer s disease based on Voyager s patented method of treatment. Memryte, which Voyager is developing under this agreement, is currently in Phase III clinical trials.

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. CHRONOGESIC completed a pilot Phase III clinical trial. Clinical trials have been suspended pending system redesign.

DURECT Research Programs

We are also currently researching and developing 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.

Collaborative Research and Development Revenues

We generate substantially all collaborative research and development revenues from three collaborative agreements related to the development and commercialization of pharmaceutical systems based on our technologies: one with Endo related to TRANSDUR-Sufentanil, one with Pain Therapeutics related to Remoxy, and one with Voyager related to Memryte.

Product Revenues

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

- ALZET osmotic pumps for animal research use; and
- LACTEL biodegradable polymers which are used by our customers as raw materials in their pharmaceutical and medical products. This product line was sold through our wholly-owned subsidiary API until it was merged with and into Durect as of December 31, 2004.

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 March 31, 2006, we had an accumulated deficit of $188.3 million. Our net loss for the three months ended March 31, 2006 was $6.3 million. Our losses were $18.1 million, $27.6 million and $22.7 million for the twelve months ended December 31, 2005, 2004 and 2003, 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 animal 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 to comply with corporate governance requirements and in stock-based compensation cost related to selling, general and administrative personnel under SFAS 123(R). We also expect to incur additional non-cash expenses relating to amortization of intangible assets. We do not anticipate revenues from our pharmaceutical systems, should they be approved, for at least 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.

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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.

Revenue from the sale of intellectual property rights is recognized upon assignment of such rights by us to a third party, provided the collectibility is assured and we have no future performance obligations related to such rights, except for the on-going de minimus assistance we would provide to the third party with respect to the maintenance of such rights.

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 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. 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.

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. 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.

Revenue on cost-plus-fee contracts, such as under contracts to perform research and development for others, is recognized only to the extent of reimbursable costs incurred plus estimated fees thereon. In all cases, revenue is recognized only after a signed agreement is in place.

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.

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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, 2005. However, there can be no assurance that at the time other periodic reviews are completed, a material impairment charge will not be recorded.

Accrued Liabilities and Contract Research Liabilities

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

Stock-Based Compensation

Prior to January 1, 2006, we accounted for our stock-based employee compensation plans under the measurement and recognition provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees,* and related Interpretations, as permitted by Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation.* We recorded no stock-based employee compensation expense for options granted under our six incentive plans prior to January 1, 2006 as all options granted under those plans had exercise prices equal to the fair market value of our common stock on the date of grant. We also recorded no compensation expense in connection with our employee stock purchase plan as the purchase price of the stock was not less than 85% of the lower of the fair market value of our common stock at the beginning of each offering period or at the end of each purchase period. In accordance with SFAS 123 and SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure,* we disclosed our loss and net loss per share as if we had applied the fair value-based method in measuring compensation expense for our stock-based compensation plans.

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

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January 1, 2006, we amortize the fair value on an accelerated basis. For options granted on or after January 1, 2006, we amortize the fair value on a straight-line basis. All options are amortized over the requisite service periods of the awards, which are generally the vesting periods. We may elect to use different assumptions under the Black-Scholes option valuation model in the future, which could materially affect our net income or loss and net income or loss per share.

Results of Operations

Three months ended March 31, 2006 and 2005

Revenues. Net revenues were $5.2 million and $5.4 million for the three months ended March 31, 2006 and 2005, respectively. The decrease in total revenues is primarily attributable to lower collaborative research and development revenue recognized from our agreements with Voyager Pharmaceutical Corporation and Endo Pharmaceuticals, Inc., offset by higher product revenues from our ALZET product lines.

Collaborative research and development and other revenue

We also recognize revenues from collaborative research and development activities and service contracts. We recorded $3.1 million of collaborative research and development revenue for the three months ended March 31, 2006 compared to $3.6 million for the same period in 2005. 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. The decrease in collaborative research and development revenue in the three months ended March 31, 2006 was primarily attributable to our decreased development activities for Memryte (collaboration with Voyager) and TRANSDUR-Sufentanil (collaboration with Endo), offset by higher collaborative research and development revenue recognized in connection with our agreement for Remoxy (collaboration with Pain Therapeutics) compared with the same period in 2005.

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. 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 the future years pending our third party collaborators commitment and progress to the research and development programs, although we will continue to increase our efforts to develop products with in connection with various strategic collaborations. The collaborative research and development revenues associated with our major collaborators are as follows (in thousands):

	Three months ended March 31,	
	2006	2005
Partner		
Endo Pharmaceuticals, Inc. (1)	$ 790	$ 1,086
Pain Therapeutics, Inc.	1,822	1,194
Voyager Pharmaceutical Corporation	299	1,004
Others	147	313
Total collaborative research and development revenue	$ 3,058	$ 3,597

Notes:

1. Amounts related to the up-front fee were $547,000 and $155,000 for the three months ended March 31, 2006 and 2005, respectively. The amount included in the first quarter of 2005 represented the amount recognized over the period from March 10, 2005 to March 31, 2005

since the license agreement with Endo relating to TRANSDUR-Sufentanil was executed on March 10, 2005.

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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.

Other revenue from service contracts was zero and $41,000 in the three months ended March 31, 2006 and 2005. Service contract revenues were related to certain polymer related service contracts we signed with various customers through API, our former subsidiary. The decrease was primarily due to completion of certain service contracts in the second half of 2005. We do not expect to increase our effort to generate significant revenue from our service contracts related to polymer business in the future.

Product revenue

A portion of our revenues is derived from our product sales, which include our ALZET mini pump product line, and to a lesser extent our biodegradable polymer products. Net product revenues were $2.2 million in the three months ended March 31, 2006 compared to $1.8 million for the same period in 2005. The increase was primarily due to higher product revenue from our ALZET mini pump product line due to a greater number of units sold and slightly higher polymer sales in the three months ended March 31, 2006 compared with the same period in 2005.

Cost of revenues. Cost of revenues was $829,000 and $671,000 for the three months ended March 31, 2006 and 2005, respectively. Cost of revenues includes cost of product revenue from our ALZET mini pump product line and our biodegradable polymer products and, to a lesser extent, cost of certain polymer related service contracts through API, our former subsidiary. The increase in the cost of revenues was primarily due to higher product revenue from our existing commercial product lines in the three months ended March 31, 2006. Stock based compensation expense related to cost of revenue was $8,000 recognized under SFAS 123(R) in the three months ended March 31, 2006.

Cost of revenues associated with the product revenue increased to $829,000 in the first three months of 2006 from $578,000 in the same period in 2005, primarily as the result of an increase in product revenue of our ALZET mini pump product line. Cost of service revenue was zero for the three months ended March 31, 2006 and $93,000 for the same period in 2005 due to a decline in our service contract revenue related to our polymer business. As of March 31, 2006 and 2005, we had 20 manufacturing employees. We expect cost of revenues to remain comparable in the future, as we do not expect product revenues to increase significantly in the 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 $7.2 million and $6.7 million for the three months ended March 31, 2006 and 2005, respectively. The increase in the three months ended March 31, 2006 was primarily attributable to the higher employee costs and higher development expenses for SABER-Bupivacaine and Remoxy, partially offset by lower development expenses for TRANSDUR-Sufentanil and Memryte, compared with the same period in 2005. The increase was also attributable to the stock-based compensation expense of $614,000 related to research and development personnel under SFAS 123(R) in the first quarter of 2006, compared to none in first quarter of 2005.

In the first quarter of 2006, we incurred higher research and development expenses for SABER-Bupivacaine associated with Phase II clinical trials in Australia and U.K. and other development activities compared with the same period 2005. We incurred lower development expenses for TRANSDUR-Sufentanil in the first quarter of 2006 compared with the same period in 2005 as Endo performed the majority of the development work for this product after the license agreement was signed in March 2005. We also incurred higher research and development expenses for Remoxy in the first quarter of 2006 to support the development activities related the development activities for Remoxy and formulation work related to other opioids products compared with the same period in 2005. We incurred lower research and development expenses in the first quarter of 2006 for Memryte compared with the same period in 2005 due to the reduced formulation development work for Voyager as the program moved to Phase III clinical trials.

As of March 31, 2006, we had 88 research and development employees compared with 79 as of the corresponding date in 2005. 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 cost related to research and development personnel under SFAS 123(R).

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

	Three months ended March 31,	
	2006	2005
SABER-Bupivacaine	$ 2,055	$ 1,302
TRANSDUR-Sufentanil	324	2,361
Remoxy	1,389	906
Memryte	244	1,052
CHRONOGESIC	470	392
Others(1)	2,682	651
Total research and development expenses	$ 7,164	$ 6,664

Note (1): Includes stock-based compensation expenses of $614,000 and $46,000 for the three months ended March 31, 2006 and 2005, respectively.

We cannot reasonably estimate the timing and costs of our research and development programs due to the risks and uncertainties associated with developing pharmaceutical systems as outlined in the Risk Factors section of this report. The duration of development of our research and development programs may span as many as ten years or more, and estimation of completion dates or costs to complete would be highly speculative and subjective due to the numerous risks and uncertainties associated with developing pharmaceutical products, including significant and changing government regulation,

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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 $3.0 million for the three months ended March 31, 2006, compared to $2.5 million for the same period in 2005. The increase in the three months ended March 31, 2006 was primarily attributable to the higher product assessment and market research related expenses as well as the stock-based compensation expense of $321,000 related to selling, general and administrative personnel recognized under SFAS 123(R) in the first quarter of 2006.

As of March 31, 2006, we had 32 selling, general and administrative personnel compared with 30 as of the corresponding date in 2005. 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 to comply with corporate governance requirements 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 $300,000 and $303,000 for the three-month periods ended March 31, 2006 and 2005, respectively. The amortization of intangible assets decreased slightly in the three months ended March 31, 2006 as certain intangible assets were fully amortized in the quarter ended September 30, 2005. We continue to amortize the existing intangible assets at a constant rate over their estimated useful lives. In 2005, goodwill was evaluated for impairment in accordance with SFAS 142. Based on our evaluation, no indicators of impairment were noted. Should goodwill become impaired in the future, we may be required to record an impairment charge to write the goodwill down to its estimated fair value.

The net amount of other intangible assets at March 31, 2006 was $235,000, which will be amortized as follows: $123,000 for the year ending December 31, 2006, $31,000 in each of the years ending December 31, 2007, 2008 and 2009, and $19,000 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 for the three months ended March 31, 2006, compared with $485,000 for the same period in 2005. The increase in interest income was primarily the result of higher yields as well as higher average cash and investment balances during the three months ended March 31, 2006 compared with the same period in 2005. Interest expense was $1.1 million for the three months ended March 31, 2006 and 2005. The interest expense was primarily due to the interest accrued on our convertible notes issued in 2003.

Liquidity and Capital Resources

We had cash, cash equivalents and investments totaling $87.9 million at March 31, 2006 compared to $91.0 million at December 31, 2005. These balances include $1.7 million and $2.0 million of interest-bearing marketable securities classified as restricted investments on our balance sheets as of March 31, 2006 and December 31, 2005, respectively. The decrease in cash, cash equivalents and investments during the three months ended March 31, 2006 was primarily the result of ongoing operating expenses, partially offset by payments received from customers.

Working capital was $72.9 million and $84.2 million at March 31, 2006 and December 31, 2005, respectively. The decrease was primarily attributable our operating expenditures in the three months ended March 31, 2006.

We used $3.3 million of cash for operations for the three months ended March 31, 2006 compared to $5.2 million for the corresponding period in 2005. 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 increase in cash collected from our third party collaborators for the three months ended March 31, 2006 compared to the same period in 2005.

We used $18.9 million of cash in investing activities for the three months ended March 31, 2006 compared to $3.7 million of cash provided by investing activities in the corresponding period in 2005. The decrease in cash provided by investing activities was primarily due to an increase in purchases of short-term and long-term investments net of proceeds from maturities of these investments for the three months ended March 31, 2006 compared to the same period in 2005.

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We received $786,000 of cash from financing activities for the three months ended March 31, 2006 compared to $11,000 for the corresponding period in 2005. The increase was primarily due to higher proceeds from exercises of stock options in the three months ended March 31, 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 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.

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 obligation 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 purpose, including working capital and capital expenditures. In 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. 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 market conditions. As of March 31, 2006, the remaining principal balance of our convertible subordinated notes was $57.3 million.

In conjunction with the acquisition of Southern BioSystems, Inc. (SBS) in April 2001, we assumed Alabama State Industrial Development Bonds (SBS Bonds) with remaining principal payments of $1.7 million and a current 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 the 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 March 31, 2006, the remaining principal payments of the bonds were $875,000.

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

During the three months ended March 31, 2006, 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, 2005.

We also anticipate incurring capital expenditures of at least $3 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:

- the public equity market;

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private equity financing;

collaborative arrangements; and

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.

Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations. We select investments that maximize interest income to the extent possible given these two constraints. We satisfy liquidity requirements by investing excess cash in securities with different maturities to match projected cash needs and limit concentration of credit risk by diversifying our investments among a variety of high credit-quality issuers.

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ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Sensitivity

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

Our primary investment objective is to preserve principal while at the same time maximizing yields without significantly increasing risk. Our portfolio includes money markets funds, commercial paper, medium-term notes, corporate notes, government securities, auction rate securities, corporate bonds and market auction preferreds. The diversity of our portfolio helps us to achieve our investment objective. As of March 31, 2006, approximately 79% of our investment portfolio is composed of investments with original maturities of one year or less and approximately 50% of our investment portfolio matures less than 90 days from the date of purchase.

The following table presents the amounts of our cash equivalents and investments that may be subject to interest rate risk and the average interest rates as of March 31, 2006 by year of maturity (dollars in thousands):

	2006	2007	2008	2009	Total
Cash equivalents:					
Fixed rate	$ 41,655	$	$	$	$ 41,655
Average fixed rate	4.68%				4.68%
Variable rate	$ 69	$	$	$	$ 69
Average variable rate	4.69%				4.69%
Short-term investments:					
Fixed rate	$ 14,521	$ 5,210	$	$	$ 19,731
Average fixed rate	2.58%	4.38%			3.01%
Variable rate	$ 10,000	$	$	$	$ 10,000
Average variable rate	4.64%				4.64%
Long-term investments:					
Fixed rate	$	$ 6,866	$ 4,468	$ 996	$ 12,330
Average fixed rate		3.57%	4.88%	5.35%	4.27%
Restricted investments:					
Fixed rate	$ 1,708	$	$	$	$ 1,708
Average fixed rate	2.67%				2.67%
Total investment securities	$ 67,953	$ 12,076	$ 4,468	$ 996	$ 85,493
Average rate	3.92%	3.93%	4.88%	5.35%	4.01%

In the table above we have reflected the duration of auction rate securities (ARS) based on their reset features as of March 31, 2006.

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.

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PART II OTHER INFORMATION

ITEM 1. ***Legal Proceedings***

We are not a party to any material legal proceedings.

Item 1A. Risk Factors.

In addition to the other information in this Form 10-Q a number of factors may affect our business and prospects. These factors include but are not limited to the following, which you should consider carefully in evaluating our business and prospects.

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;

selecting and developing catheter or other targeting technology, if appropriate, to deliver the drug to a specific location within the body; and

demonstrating through clinical trials that the drug and system combination is safe and effective in patients for the intended indication.

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 our SABER-Bupivacaine, TRANSDUR-Sufentanil, 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 SABER-Bupivacaine, TRANSDUR-Sufentanil, Remoxy, Memryte, CHRONOGESIC or other pharmaceutical systems, we will not be able to earn revenue from them, which would materially harm our business.

We or our third-party collaborators must conduct and satisfactorily complete required laboratory performance and safety testing, animal studies and clinical trials for our pharmaceutical systems before they can be sold

Before we or our third-party collaborators can obtain government approval to sell any of our pharmaceutical systems, we or they, as applicable, must demonstrate through laboratory performance studies and safety testing, preclinical (animal) studies and clinical (human) trials that each system is safe and effective for human use for each targeted disease. The clinical development status of our most advanced programs is as follows:

SABER-Bupivacaine Phase I trial and dosing of first Phase II trial in Australia completed. Phase II trials on-going in the U.S. and the United Kingdom.

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TRANSDUR-Sufentanil Patch Dosing of Phase I trial and first trial of Phase II program completed.

Remoxy In February 2006, Pain Therapeutics and its commercialization sublicensee King announced that Remoxy had successfully completed a Special Protocol Assessment (SPA) with the FDA with respect to the pivotal Phase III program for Remoxy. In May 2006, Pain Therapeutics reported that during the first quarter of 2006, it commenced a pivotal Phase III program with Remoxy.

Memryte Dosing completed in one Phase I trial by Voyager. Voyager has completed one Phase II proof of concept trial using the drug but not our DURIN-based dosage form (Memryte) and has a second such trial ongoing. Voyager has initiated dosing for pivotal Phase III clinical studies using Memryte as an adjunctive therapy with acetyl cholinesterase inhibitors (ACIs) for the treatment of mild to moderate Alzheimer s disease.

CHRONOGESIC Phase I, Phase II and Pilot Phase III completed. Redesigning the system to address performance problems and expect to resume clinical trials when system design is completed.

We are currently in the 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 is 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.

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 manufacture 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 SABER Bupivacaine, TRANSDUR-Sufentanil, Remoxy, 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 systems or component at an acceptable cost, then we and our third-party collaborators may not be able to commercialize that pharmaceutical systems or we may be in breach of our supply obligations to our third-party collaborators.

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Our manufacturing facility in Cupertino is a functional multi-discipline site that we have used to manufacture only research and clinical supplies of several of our pharmaceutical systems under good manufacturing practices (GMP), including SABER-Bupivacaine, TRANSDUR-Sufentanil, DURIN-Leuprolide (Memryte), Remoxy 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 timely accomplish these tasks.

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 and our third-party collaborators, where relevant, may also need or choose to subcontract with third-party contractors to perform manufacturing steps of our pharmaceutical systems or supply required components for our pharmaceutical systems in which case 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 development products 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.

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.

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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 also 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.

Our near-term revenues depend on collaboration agreements with other companies. These agreements subject us to obligations which must be fulfilled and require us to manage complex relationships with third parties. If we are unable to meet our obligations or manage our relationships with our collaborators under these agreements or enter into additional collaboration agreements or if our existing collaborations are terminated, our revenues may decrease

Our near-term revenues are based to a significant extent on collaborative arrangements with third parties, pursuant to which we receive payments based on our performance of research and development activities and the attainment of milestones set forth in the agreements. We may not be able to fulfill our obligations or attain milestones set forth in any specific agreement, which could cause our revenues to fluctuate or be less than anticipated and may expose us to liability for contractual breach. In addition, these agreements may require us to devote significant time and resources to communicating with and managing our relationship with such collaborators and resolving possible issues of contractual interpretation which may detract from time our management would otherwise devote to our 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 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, 2007 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, 2007.

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

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We depend to a large extent on third-party collaborators, and we do not have or have limited 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 and Voyager under which we granted such third parties the right to develop, apply for regulatory approval for, market, promote or distribute Remoxy and Memryte, respectively, subject to payments to us in the form of product royalties and other payments. We have limited or no control over the expertise or resources that any collaborator may devote to the development, marketing or sale of these pharmaceutical systems, or the timing of their activities. Any of our present or future collaborators may not perform their obligations as expected. These collaborators may breach or terminate their agreement with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. Further, our collaborators may elect not to develop or commercialize pharmaceutical systems arising out of our collaborative arrangements or not devote sufficient resources to the development, manufacture, marketing or sale of these pharmaceutical systems. If any of these events occur, we may not be able to develop our technologies or recognize revenue from the commercialization of our pharmaceutical systems based on such collaborations. In addition, these third parties may have similar or competitive products to the ones which are the subject of their collaborations with us, or relationships with our competitors, which may reduce their interest in developing or selling our pharmaceutical systems. We may not be able to control public disclosures made by some of our third-party collaborators, which could negatively impact our stock price.

We may develop our own sales force to market our SABER-Bupivacaine 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 SABER-Bupivacaine 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 effectively sell our pharmaceutical systems

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 or our pharmaceutical systems resulting in significant quarter-to-quarter variability in our sales.

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

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

We rely on third-party contract research organizations, service providers and suppliers to provide critical services to support development, clinical testing, and manufacturing of our pharmaceutical systems. For example, we currently depend on third-party vendors to manage and monitor our clinical trials and to perform critical manufacturing steps for our pharmaceutical systems. 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 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.

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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 SABER-Bupivacaine, TRANSDUR-Sufentanil, Remoxy, 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 SABER-Bupivacaine, Remoxy 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 systems 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 time delivery.

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 and delay new product introductions and could harm our reputation.

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

As of March 31, 2006, we had approximately $57.3 million in long-term convertible subordinated notes which mature in June 2008, $129,000 in non-current lease obligations and $675,000 in non-current bonds payable. Our substantial indebtedness, which totals $58.0 million, 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. Adverse occurrences related to our product development efforts will adversely impact our ability to meet our obligations to repay the principal amounts on our convertible subordinated notes when due in June 2008. In addition, 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. If we are unable to satisfy our debt service requirements, substantial liquidity problems could result. As of March 31, 2006, we had cash and investments valued at approximately $87.9 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 obligations when they become due and may have to 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 restructure our obligations, we may be forced

to seek protection under applicable bankruptcy laws. Any restructure or bankruptcy could materially impair the value of our common stock.

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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 $57.3 million in outstanding principal, plus any accrued but unpaid interest on our outstanding convertible promissory 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 National Market or any similar United States system of automated dissemination of quotations of securities prices, or,

- 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 National 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.

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

We have incurred significant operating losses since our inception in 1998 and, as of March 31, 2006, had an accumulated deficit of approximately $188.3 million. We expect to continue to incur significant operating losses over the next several years as we continue to incur costs for research and development, clinical trials and manufacturing. 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 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 receive significant revenue in the near future. Our current product revenues are from the sale of the ALZET product we acquired in April 2000 from ALZA and the sale of biodegradable polymers. We do not expect these product revenues to increase significantly in future periods. 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.

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

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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 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; and

costs for recruiting and retaining employees and consultants.

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 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 April 28, 2006, we held 26 issued U.S. patents and 70 issued foreign patents (which include granted European patent rights that have been validated in various EU member states). In addition, we have 33 pending U.S. patent applications and have filed 55 patent applications under the Patent Cooperation Treaty, from which 102 national phase applications are currently pending in Europe, Australia, Japan, Canada, Mexico, New Zealand, Brazil, Israel, India, Hong Kong 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 of ALZA 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.

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 agreement based on the exclusivity that our intellectual property rights confer on the products being developed. The loss or diminishment 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 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, a decision by the Supreme Court adverse to the patent holder in the case of MedImmune, Inc. v. Genentech, Inc., U.S. Supreme Court No. 05-608 (Feb. 21, 2006) 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.

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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 development products infringe on their intellectual property rights, particularly because there is substantial uncertainty about the validity and breadth of medical patents

We 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 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, 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. Intellectual property litigation or claims could force us to do one or more of the following, any of which could harm our business or financial results:

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

We may be required to obtain rights to certain drugs

Some of the pharmaceutical systems that we 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;

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- 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 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 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 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 2005 and determined that goodwill was not impaired as of December 31, 2005. 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 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

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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 agreement with ALZA limits our fields of operation for our DUROS-based pharmaceutical systems and gives ALZA a first right to negotiate to distribute selected products for us

Our agreement with ALZA gives us exclusive rights to develop, commercialize and manufacture products using ALZA s DUROS technology to deliver by catheter:

- drugs to the central nervous system to treat select nervous system disorders;
- drugs to the middle and inner ear;
- drugs to the pericardial sac of the heart; and
- select drugs into vascular grafts.

We also have the right to use the DUROS technology to deliver systemically and by catheter:

sufentanil to treat chronic pain; and

select cancer antigens.

We may not develop, manufacture or commercialize DUROS-based pharmaceutical systems outside of these specific fields without ALZA s prior approval. In addition, if we develop or commercialize any drug delivery technology for use in a manner similar to the DUROS technology in a field covered in our license agreement with ALZA, then we may lose our exclusive rights to use the DUROS technology in such field as well as the right to develop new pharmaceutical systems using DUROS technology in such field. In order to maintain commercialization rights for our products on a worldwide basis, we must diligently develop our pharmaceutical systems, procure required regulatory approvals and commercialize the pharmaceutical systems in selected major market countries. If we fail to meet commercialization diligence requirements, we may lose rights for products in some or all countries, including the United States. These rights would revert to ALZA, which

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could then develop DUROS-based pharmaceutical products in such countries itself or license others to do so. In addition, in the event that our rights terminate with respect to any product or country, or this agreement terminates or expires in its entirety (except for termination by us due to a breach by ALZA), ALZA will have the exclusive right to use all of our data, rights and information relating to the products developed under the agreement as necessary for ALZA to commercialize these products, subject to the payment of a royalty to us based on the net sales of the products by ALZA.

Our agreement with ALZA gives us the right to perform development work and manufacture the DUROS pump component of our DUROS-based pharmaceutical systems. In the event of a change in our corporate control, including an acquisition of us, our right to manufacture and perform development work on the DUROS pump would terminate and ALZA would have the right to manufacture and develop DUROS systems for us so long as ALZA can meet our specification and supply requirements following such change in control.

Under the ALZA agreement, we must pay ALZA royalties on sales of DUROS-based pharmaceutical systems we commercialize and a percentage of any up-front license fees, milestone or special fees, payments or other consideration we receive, excluding research and development funding. In addition, commencing upon the commercial sale of a product developed under the agreement, we are obligated to make minimum product payments to ALZA on a quarterly basis based on our good faith projections of our net product sales of the product. These minimum payments will be fully credited against the product royalty payments we must pay to ALZA.

ALZA may obtain from us, for its own behalf or on behalf of one of its affiliates, the exclusive right to develop and commercialize a product in a field of use exclusively licensed to us, provided that such product does not incorporate a drug in the same drug class and is not intended for the same therapeutic indication as a product which is then being developed or commercialized by us or for which we have made commitments to a third-party. In the event that ALZA or an affiliate commercializes such a product, ALZA or its affiliate will pay us a royalty on sales of such product at a specified rate.

ALZA also has an exclusive option to distribute any DUROS-based pharmaceutical system we develop to deliver non-proprietary cancer antigens worldwide. The terms of any distribution arrangement have not been set and are to be negotiated in good faith between ALZA and us. ALZA s option to acquire distribution rights limits our ability to negotiate with other distributors for these products and may result in lower payments to us than if these rights were subject to competitive negotiations. We must allow ALZA an opportunity to negotiate in good faith for commercialization rights to our products developed under the agreement prior to granting these rights to a third-party. These rights do not apply to products that are subject to ALZA s option or products for which we have obtained funding or access to a proprietary drug from a third-party to whom we have granted commercialization rights prior to the commencement of human clinical trials.

ALZA has the right to terminate the agreement in the event that we breach a material obligation under the agreement and do not cure the breach in a timely manner. In addition, ALZA has the right to terminate the agreement if at any time prior to July 2006, we solicit for employment or hire, without ALZA s consent, a person who is or within the previous 180 days has been an employee of ALZA in the DUROS technology group.

We do not control ALZA s ability to develop and commercialize DUROS technology outside of fields licensed to us, and problems encountered by ALZA could result in negative publicity, loss of sales and delays in market acceptance of our DUROS-based pharmaceutical systems

ALZA retains complete rights to the DUROS technology for fields outside the specific fields licensed to us. Accordingly, ALZA may develop and commercialize DUROS-based products or license others to do so, so long as there is no conflict with the rights granted to us. ALZA received FDA approval to market its first DUROS-based product, VIADUR (leuprolide acetate implants) for the palliative treatment of advanced prostate cancer in March 2000. If ALZA or its commercialization collaborators, Bayer, fails to commercialize this product successfully, or encounters problems associated with this product, negative publicity could be created about all DUROS-based products, which could result in harm to our reputation and cause reduced sales of our DUROS-based pharmaceutical systems. In addition, if any third party that may be licensed by ALZA fails to develop and commercialize DUROS-based products successfully, the success of all DUROS-based systems could be impeded, including ours, resulting in delay or loss of revenue or damage to our reputation, any one of which could harm our business.

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

Our corporate headquarters, 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. 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 SABER-Bupivacaine, TRANSDUR-Sufentanil, Remoxy, DURIN-Leuprolide (Memryte) and CHRONOGESIC. Even if approved for marketing, our pharmaceutical systems may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we are developing;
- the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products, including oral medication, transdermal drug delivery products such as drug patches, or external or implantable drug delivery products; and

pricing and reimbursement policies of government and third-party 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.

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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, including proposed changes in accounting for employee stock-based awards, 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 National Market rules, are creating uncertainty for companies such as ours and insurance, accounting and auditing costs are increasing as a result of this uncertainty and other factors. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Risks Related To Our Common Stock

Our operating history makes evaluating our stock difficult

We have engaged primarily in research and development, licensing technology, raising capital and recruiting scientific and management personnel and, to a lesser extent, sales and marketing of products that we do not consider core to our business. We have no approved pharmaceutical system products. This history does not enable investors to fully assess our ability to successfully develop our pharmaceutical systems, achieve market acceptance of our pharmaceutical systems and respond to competition. Furthermore, we anticipate that our quarterly and annual results of operations will fluctuate for the foreseeable future. We believe that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties encountered by companies with no approved pharmaceutical products, particularly companies in new and rapidly evolving markets such as pharmaceuticals, drug delivery and biotechnology. To address these risks, we must, among other things, obtain regulatory approval for and

commercialize our pharmaceutical systems, which may not occur. We may not be successful in addressing these risks and difficulties. We may require additional funds to complete the development of our pharmaceutical systems and to fund operating losses to be incurred in the next several years.

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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 remaining $57.3 million aggregate principal amount of convertible subordinated 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 convertible debt securities. 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 in the open market. These transactions could dilute existing stockholders and increase the volatility of our stock

To the extent we are able to do so on terms favorable to us, we may choose to purchase a portion of our outstanding 6.25% Convertible Subordinated Notes due June 2008 from time to time in privately negotiated transactions under Section 3(a)(9) of the Securities Act of 1933. On July 21, 2005, we entered into an agreement for such a transaction for notes with an aggregate principal amount of up to $5.0 million. 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.

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 Pharmaceuticals, Pain Therapeutics or Voyager Pharmaceuticals) to develop and commercialize successfully the respective pharmaceutical systems they are developing;
- adverse results or delays in our clinical trials of SABER-Bupivacaine, TRANSDUR-Sufentanil, Remoxy, 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;

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

developments concerning our strategic alliances or acquisitions;

actual or anticipated variations in our operating results;

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

deviations in our operating results from the estimates of analysts;

sales of our common stock by our executive officers, 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.

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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.

Our trading volume is relatively low and may contribute to its volatility

The average daily trading volume of our common stock for the year ended March 31, 2006, was 454,271 shares. The limited trading volume of our stock may contribute to its volatility, and an active trading market in our stock might not continue. 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 convertible subordinated notes 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.

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 entities affiliated with them 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;

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prohibiting stockholder action by written consent; and

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

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

None

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

None

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

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 Jian Li.
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 Jian Li.

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SIGNATURES

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

DURECT CORPORATION

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

Chief Executive Officer

Date: May 10, 2006

By: /s/ JIAN LI
Jian Li
Vice President, Finance and Corporate Controller

(Principal Financial and Accounting Officer)

Date: May 10, 2006