DURECT CORP
Form 10-Q
May 09, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2007

OR

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

For the transition period from to

Commission file number 000-31615

DURECT CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**94-3297098**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2 Results Way

Cupertino, California 95014

(Address of principal executive offices, including zip code)

(408) 777-1417

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by a check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.). Yes ¨ No x

As of April 30, 2007, there were 69,401,796 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, 2007 (unaudited)	December 31, 2006 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,386	$ 41,554
Short-term investments	34,800	28,297
Accounts receivable, net of allowances of $59 and $1, respectively	4,674	2,152
Inventories	2,042	2,052
Prepaid expenses and other current assets	1,565	1,744
Total current assets	76,467	75,799
Property and equipment, net	7,429	7,451
Goodwill	6,399	6,399
Intangible assets, net	104	111
Long-term investments	2,948	10,472
Restricted investments	1,284	1,284
Other long-term assets	855	969
Total assets	$ 95,486	$ 102,485
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 922	$ 864
Accrued liabilities	3,586	4,522
Contract research liability	3,125	1,624
Interest payable on convertible notes	681	97
Deferred revenue, current portion	5,254	5,348
Equipment financing obligations, current portion	35	34
Bonds payable, current portion	210	210
Total current liabilities	13,813	12,699
Equipment financing obligations, noncurrent portion	132	141
Bonds payable, noncurrent portion	465	465
Convertible subordinated notes	37,337	37,337
Deferred revenue, noncurrent portion	13,197	14,507
Other long-term liabilities	273	304
Commitments		
Stockholders equity:		
Common stock, $0.0001 par value: 110,000 shares authorized; 69,261 and 69,212 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively	7	7
Additional paid-in capital	267,872	265,896

Deferred royalties and commercial rights	(13,480)	(13,480)
Accumulated other comprehensive loss	(17)	(45)
Accumulated deficit	(224,113)	(215,346)
Stockholders equity	30,269	37,032
Total liabilities and stockholders equity	$ 95,486	$ 102,485

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

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DURECT CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	Three months ended March 31, 2007	Three months ended March 31, 2006
Collaborative research and development and other revenue	$ 3,458	$ 3,058
Product revenue, net	2,268	2,153
Total revenues	5,726	5,211
Operating expenses:		
Cost of revenues (1)	860	829
Research and development (1)	10,352	7,164
Selling, general and administrative (1)	3,538	3,005
Amortization of intangible assets	7	300
Total operating expenses	14,757	11,298
Loss from operations	(9,031)	(6,087)
Other income (expense):		
Interest and other income	978	906
Interest expense	(714)	(1,077)
Net other income (expense)	264	(171)
Net loss	$ (8,767)	$ (6,258)
Net loss per share, basic and diluted	$ (0.13)	$ (0.10)
Shares used in computing basic and diluted net loss per share	69,231	61,837

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

	2007	2006
Cost of revenues	$ 34	$ 8
Research and development	1,156	614
Selling, general and administrative	668	321
Total stock-based compensation	$ 1,858	$ 943

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, 2007	Three months ended March 31, 2006
Cash flows from operating activities		
Net loss	$ (8,767)	$ (6,258)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	533	511
Amortization	7	300
Stock-based compensation	1,858	943
Changes in assets and liabilities:		
Accounts receivable	(2,522)	1,324
Inventories	13	73
Prepaid expenses and other assets	293	1,802
Accounts payable	58	(806)
Accrued liabilities and other long-term liabilities	(967)	(716)
Contract research liability	1,501	(757)
Interest payable on convertible notes	584	896
Deferred revenue	(1,404)	(642)
Total adjustments	(46)	2,928
Net cash and cash equivalents used in operating activities	(8,813)	(3,330)
Cash flows from investing activities		
Purchases of property and equipment	(511)	(633)
Purchases of available-for-sale securities	(10,700)	(28,185)
Proceeds from maturities of available-for-sale securities	11,749	9,913
Net cash and cash equivalents provided by (used in) investing activities	538	(18,905)
Cash flows from financing activities		
Payments on term loan and equipment financing obligations	(8)	(64)
Net proceeds from issuances of common stock through exercise of options	115	850
Net cash and cash equivalents provided by financing activities	107	786
Net decrease in cash and cash equivalents	(8,168)	(21,449)
Cash and cash equivalents, beginning of the period	41,554	65,542
Cash and cash equivalents, end of the period	$ 33,386	$ 44,093

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

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DURECT CORPORATION

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 1. Summary of Significant Accounting Policies

Nature of Operations

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

Basis of Presentation

The accompanying unaudited condensed financial statements include the accounts of the Company. These financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and therefore, do not include all the information and footnotes necessary for a complete presentation of the Company s results of operations, financial position and cash flows in conformity with U.S. generally accepted accounting principles (U.S. GAAP). The unaudited financial statements reflect all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair presentation of the financial position at March 31, 2007, the operating results for the three months ended March 31, 2007 and 2006, and cash flows for the three months ended March 31, 2007 and 2006. The condensed balance sheet as of December 31, 2006 has been derived from audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These financial statements and notes should be read in conjunction with the Company s audited financial statements and notes thereto, included in the Company s annual report on Form 10-K filed with the SEC.

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

Reclassifications

Certain prior period amounts for stock-based compensation related to research and development expense in the footnotes to the financial statements have been reclassified to conform to current period presentation. Such reclassification did not impact the Company s net loss or financial position.

Inventories

Inventories are stated at the lower of cost or market, with cost determined on a first-in, first-out basis.

Inventories consisted of the following (in thousands):

	March 31, 2007 (unaudited)	December 31, 2006
Raw materials	$ 209	$ 185
Work in process	525	711
Finished goods	1,308	1,156
Total inventories	$ 2,042	$ 2,052

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS 123(R), *Share-Based Payment,* using the modified prospective transition method. Under that transition method, compensation cost recognized in the three 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 SEC issued Staff Accounting Bulletin (SAB) No. 107, which provides supplemental implementation guidance for SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R).

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.

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

Revenue Recognition

Revenue from the sale of products is recognized at the time the product is shipped and title transfers to customers, provided no continuing obligation exists and the collectibility of the amounts owed is reasonably assured.

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

Research and development revenue related to services performed under the collaborative arrangements with the Company s third-party collaborators is recognized as the related research and development services are performed. These research payments received under each respective agreement are not refundable and are generally based on reimbursement of qualified expenses, as defined in the agreements. Of note, in regards to the Company s collaboration with Nycomed, in contrast to the Company s other collaborations, because the Company and Nycomed jointly control and fund the development of POSIDUR, the Company will not recognize revenue from the reimbursement of qualified research expenses from Nycomed but instead those reimbursements receivable from Nycomed will be recorded as a reduction in research and development expense. Research and development expenses under the collaborative research and development agreements generally approximate or exceed the revenue recognized under such agreements over the term of the respective agreements. Deferred revenue may result when the Company does not expend the required level of effort during a specific period in comparison to funds received under the respective agreement.

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

	Three months ended March 31,	
	2007	**2006**
Partner		
Endo Pharmaceuticals, Inc. (1)	$ 1,196	$ 790
Pain Therapeutics, Inc.	1,353	1,822
Voyager Pharmaceutical Corporation		299
Nycomed (2)	763	
Others	146	147
Total collaborative research and development revenue	$ 3,458	$ 3,058

Notes:

(1) Amounts shown include amortization of up-front fees equal to $547,000 for each of the three months ended March 31, 2007 and 2006.

(2) Amounts shown include amortization of up-front fees equal to $763,000 and $0 for the three months ended March 31, 2007 and 2006 respectively. Research and development expenses incurred by the Company in conjunction with the Nycomed collaboration and reimbursable by Nycomed are recorded as a reduction to total research and development expense.

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

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

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

Research and Development Expenses

Research and development expenses are primarily comprised of salaries and benefits associated with research and development personnel, overhead and facility costs, preclinical and non-clinical development costs, clinical trial and related clinical manufacturing costs, contract services, and other outside costs. Research and development costs are expensed as incurred. Research and development costs paid to third parties under sponsored research agreements are recognized as expense as the related services are performed, generally ratably over the period of service.

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

	Three months ended March 31,