

DURECT CORP
Form 10-Q
August 08, 2008
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2008

OR

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number 000-31615

DURECT CORPORATION

(Exact name of registrant as specified in its charter)

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Delaware
(State or other jurisdiction of
incorporation or organization)

94-3297098
(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 NO

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

Large accelerated filer Accelerated filer Smaller reporting company Non-accelerated filer

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

As of July 31, 2008, there were 81,769,675 shares of the registrant's Common Stock outstanding.

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Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements.**

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	June 30, 2008 (unaudited)	December 31, 2007 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 31,445	\$ 37,589
Short-term investments	10,859	19,710
Accounts receivable (net of allowances of \$47 and \$49, respectively)	3,080	3,622
Inventories	2,653	1,963
Prepaid expenses and other current assets	1,723	1,904
Total current assets	49,760	64,788
Property and equipment, net	6,988	7,658
Goodwill	6,399	6,399
Intangible assets, net	182	180
Long-term investments	4,259	3,697
Restricted investments	1,018	1,020
Other long-term assets	274	278
Total assets	\$ 68,880	\$ 84,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 749	\$ 1,834
Accrued liabilities	6,812	5,499
Contract research liability	678	1,946
Deferred revenue, current portion	5,768	5,728
Convertible subordinated notes		23,599
Other short-term liabilities	425	482
Total current liabilities	14,432	39,088
Deferred revenue, non-current portion	6,649	9,268
Other long-term liabilities	982	1,083
Commitments		
Stockholders' equity:		
Common stock	8	7
Additional paid-in capital	316,345	287,689
Deferred royalties and commercial rights	(13,480)	(13,480)
Accumulated other comprehensive income	23	50
Accumulated deficit	(256,079)	(239,685)
Stockholders' equity	46,817	34,581

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Total liabilities and stockholders' equity	\$ 68,880	\$ 84,020
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The accompanying notes are an integral part of these condensed financial statements.

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DURECT CORPORATION
CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2008	2007	2008	2007
Collaborative research and development and other revenue	\$ 3,867	\$ 11,408	\$ 8,136	\$ 14,866
Product revenue, net	2,436	2,024	4,605	4,292
Total revenues	6,303	13,432	12,741	19,158
Operating expenses:				
Cost of revenues (1)	982	778	1,804	1,638
Research and development (1)	9,898	9,630	19,532	19,982
Selling, general and administrative (1)	4,074	3,683	7,953	7,221
Amortization of intangible assets	12	8	23	15
Total operating expenses	14,966	14,099	29,312	28,856
Loss from operations	(8,663)	(667)	(16,571)	(9,698)
Other income (expense):				
Interest and other income	368	908	936	1,886
Interest and other expense	(304)	(720)	(759)	(1,434)
Net other income	64	188	177	452
Net loss	\$ (8,599)	\$ (479)	\$ (16,394)	\$ (9,246)
Net loss per share, basic and diluted	\$ (0.11)	\$ (0.01)	\$ (0.22)	\$ (0.13)
Shares used in computing basic and diluted net loss per share	75,430	69,364	74,772	69,298

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

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

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

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DURECT CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

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

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

Table of Contents**DURECT CORPORATION****NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS****Note 1. Summary of Significant Accounting Policies***Nature of Operations*

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

Basis of Presentation

The accompanying unaudited condensed financial statements include the accounts of the Company. These financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC), and therefore, do not include all the information and footnotes necessary for a complete presentation of the Company's results of operations, financial position and cash flows in conformity with U.S. generally accepted accounting principles (U.S. GAAP). The unaudited condensed financial statements reflect all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair presentation of the financial position at June 30, 2008, the operating results for the three and six months ended June 30, 2008 and 2007, and cash flows for the six months ended June 30, 2008 and 2007. The balance sheet as of December 31, 2007 has been derived from audited financial statements at that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These condensed financial statements and notes should be read in conjunction with the Company's audited financial statements and notes thereto, included in the Company's annual report on Form 10-K filed with the SEC.

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

Reclassifications

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

Inventories

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

Inventories consisted of the following (in thousands):

	June, 30 2008 (unaudited)	December 31, 2007
Raw materials	\$ 560	\$ 157
Work in process	1,012	666
Finished goods	1,081	1,140
Total inventories	\$ 2,653	\$ 1,963

During the first six months of 2008, the Company began to manufacture commercial lots of certain key components that are included in Remoxy to meet the anticipated requirements for these components. In addition, during the second quarter of 2008 the Company made its first shipment of these materials to meet the production requirements of King Pharmaceuticals, which has rights to commercialize Remoxy upon approval by

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