

DURECT CORP
Form 10-Q
August 08, 2014
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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, 2014

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
(State or other jurisdiction of
incorporation or organization)

94-3297098
(I.R.S. Employer
Identification No.)

10260 Bubb Road
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 check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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
Non-accelerated filer Smaller reporting company

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, 2014, there were 111,596,607 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, 2014 (unaudited)	December 31, 2013 (Note 1)
<u>ASSETS</u>		
Current assets:		
Cash and cash equivalents	\$ 18,674	\$ 7,836
Short-term investments	14,299	12,753
Accounts receivable (net of allowances of \$190 at June 30, 2014 and \$144 at December 31, 2013)	2,276	2,349
Inventories	4,554	3,502
Prepaid expenses and other current assets	751	1,888
Total current assets	40,554	28,328
Property and equipment (net of accumulated depreciation of \$20,448 and \$20,488 at June 30, 2014 and December 31, 2013, respectively)	1,826	1,985
Goodwill	6,399	6,399
Intangible assets, net	9	18
Long-term investments	4,012	3,352
Long-term restricted investments	350	450
Other long-term assets	288	288
Total assets	\$ 53,438	\$ 40,820
<u>LIABILITIES AND STOCKHOLDERS EQUITY</u>		
Current liabilities:		
Accounts payable	\$ 666	\$ 736
Accrued liabilities	4,687	5,865
Contract research liabilities	169	329
Deferred revenue, current portion	255	255
Total current liabilities	5,777	7,185
Deferred revenue, non-current portion	1,169	1,296
Long-term debt, net	19,786	
Other long-term liabilities	1,641	1,618
Commitments and contingencies		

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Stockholders' equity:		
Preferred stock		
Common stock	11	11
Additional paid-in capital	394,925	391,504
Accumulated other comprehensive income	2	1
Accumulated deficit	(369,873)	(360,795)
Stockholders' equity	25,065	30,721
Total liabilities and stockholders' equity	\$ 53,438	\$ 40,820

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

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DURECT CORPORATION
CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share amounts)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Collaborative research and development and other revenue (see Note 2)	\$ 1,735	\$ 905	\$ 5,247	\$ 1,818
Product revenue, net	2,846	3,013	5,627	6,253
Total revenues	4,581	3,918	10,874	8,071
Operating expenses:				
Cost of product revenues	1,091	1,032	2,154	2,690
Research and development	6,088	4,833	11,557	9,622
Selling, general and administrative	2,850	3,210	6,213	6,111
Total operating expenses	10,029	9,075	19,924	18,423
Loss from operations	(5,448)	(5,157)	(9,050)	(10,352)
Other income (expense):				
Interest and other income (expenses), net	3	13	6	27
Interest expense	(33)	(1)	(34)	(3)
Net other income	(30)	12	(28)	24
Net loss	\$ (5,478)	\$ (5,145)	\$ (9,078)	\$ (10,328)
Net loss per share				
Basic	\$ (0.05)	\$ (0.05)	\$ (0.08)	\$ (0.10)
Diluted	\$ (0.05)	\$ (0.05)	\$ (0.08)	\$ (0.10)
Weighted-average shares used in computing net loss per share				
Basic	110,570	101,954	110,519	101,918
Diluted	110,570	101,954	110,519	101,918
Total comprehensive loss	\$ (5,481)	\$ (5,146)	\$ (9,077)	\$ (10,331)

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

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DURECT CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six months ended	
	June 30,	
	2014	2013
Cash flows from operating activities		
Net loss	\$ (9,078)	\$ (10,328)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	310	512
Stock-based compensation	1,501	1,796
Changes in assets and liabilities:		
Accounts receivable	73	154
Inventories	(1,055)	248
Prepaid expenses and other assets	1,137	814
Accounts payable	(70)	(1,014)
Accrued and other liabilities	524	979
Contract research liabilities	(160)	(343)
Deferred revenue	(127)	(463)
Total adjustments	2,133	2,683
Net cash used in operating activities	(6,945)	(7,645)
Cash flows from investing activities		
Purchases of property and equipment	(91)	(54)
Purchases of available-for-sale securities	(10,600)	(6,790)
Proceeds from maturities of available-for-sale securities	8,495	11,200
Net cash (used in) provided by investing activities	(2,196)	4,356
Cash flows from financing activities		
Payments on equipment financing obligations	(7)	(4)
Net proceeds from issuance of long-term debt	19,786	
Net proceeds from issuances of common stock	200	87
Net cash provided by financing activities	19,979	83
Net increase (decrease) in cash and cash equivalents	10,838	(3,206)
Cash and cash equivalents, beginning of the period	7,836	11,195

Cash and cash equivalents, end of the period	\$ 18,674	\$ 7,989
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The accompanying notes are an integral part of these financial statements.

Table of Contents**DURECT CORPORATION****NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS****Note 1. Summary of Significant Accounting Policies (TO ADD RECENT ACCOUNTING PRONOUNCEMENTS)*****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 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 and excipients for pharmaceutical and medical device clients for use as raw materials in their products. In addition, the Company conducts research and development of pharmaceutical products in collaboration with third party pharmaceutical and biotechnology companies.

Basis of Presentation

The accompanying unaudited 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 June 30, 2014, the operating results and comprehensive loss for the three and six months ended June 30, 2014 and 2013, and cash flows for the six months ended June 30, 2014 and 2013. The balance sheet as of December 31, 2013 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 for the fiscal year ended December 31, 2013 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.

Inventories

Inventories are stated at the lower of cost or market, with cost determined on a first-in, first-out basis. The Company's inventories consisted of the following (in thousands):

	June 30, 2014	December 31, 2013
Raw materials	\$ 2,289	\$ 1,404
Work in process	1,070	1,063
Finished goods	1,195	1,035

Total inventories	\$ 4,554	\$ 3,502
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Revenue Recognition

Revenue from the sale of products is recognized when there is persuasive evidence that an arrangement exists, the product is shipped and title transfers to customers, provided no continuing obligation on the Company's part exists, the price is fixed or determinable and the collectability of the amounts owed is reasonably assured. The Company enters into license and collaboration agreements under which it may receive upfront license fees, research funding and contingent milestone payments and royalties. The Company's deliverables under these arrangements typically consist of granting licenses to intellectual property rights and providing research and development services. The accounting standards contain a presumption that separate contracts entered into at or near the same time with the same entity or related parties were negotiated as a package and should be evaluated as a single agreement.

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.

Table of Contents***Comprehensive Income (Loss)***

Components of other comprehensive income (loss) are comprised entirely of unrealized gains and losses on the Company's available-for-sale securities for all periods presented and are included in total comprehensive income (loss) as follows (in thousands).

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Net loss	\$ (5,478)	\$ (5,145)	\$ (9,078)	\$ (10,328)
Net change in unrealized gain on available-for-sale investments, net of tax	(3)	(1)	1	(3)
Comprehensive loss	\$ (5,481)	\$ (5,146)	\$ (9,077)	\$ (10,331)

The tax effect of the changes in accumulated other comprehensive income (loss) was immaterial for the periods presented. Accumulated other comprehensive income as of June 30, 2014 and December 31, 2013 is entirely comprised of net unrealized gains on available-for-sale securities.

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding. Diluted net income (loss) per share is computed using the weighted-average number of common shares outstanding and common stock equivalents (i.e., options to purchase common stock) outstanding during the period, if dilutive, using the treasury stock method for options and warrants.

Options to purchase approximately 20.2 million and 19.5 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the three and six months ended June 30, 2014, respectively, as the effect would be anti-dilutive. Options to purchase approximately 22.2 million and 21.6 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the three and six months ended June 30, 2013, respectively, as the effect would be anti-dilutive.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued guidance codified in ASC 606, *Revenue Recognition - Revenue from Contracts with Customers*, which amends the guidance in former ASC 605, *Revenue Recognition*. The core principle of the guidance is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The guidance provides companies with two implementation methods. Companies can choose to apply the standard retrospectively to each prior reporting period presented (full retrospective application) or retrospectively with the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings of the annual reporting period that includes the date of initial application (modified retrospective application). The standard will be effective for public entities for annual and interim periods beginning after December 15, 2016. The Company is currently evaluating the impact of the provisions of ASC 606.

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The collaborative research and development and other revenues associated with the Company's major third-party collaborators are as follows (in thousands):

Collaborator	Three months ended		Six months ended	
	June 30,	June 30,	June 30,	June 30,
	2014	2013	2014	2013
Zogenix, Inc. (Zogenix) (1)	\$ 1,383	\$ 247	\$ 2,164	\$ 499
Pain Therapeutics, Inc. (Pain Therapeutics)	246		697	1
Pfizer Inc. (Pfizer)	73		87	13
Impax Laboratories, Inc. (Impax) (2)			2,090	
Others	33	658		