DURECT CORP
Form 10-Q
August 02, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2018

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.)

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
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 30, 2018, there were 162,001,652 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)

	June 30, 2018 (unaudited)	December 31, 2017 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$37,338	$29,375
Short-term investments	5,061	7,384
Accounts receivable (net of allowances of $57 at June 30, 2018 and $155 at December 31, 2017)	1,465	2,376
Inventories, net	3,263	3,163
Prepaid expenses and other current assets	2,691	3,060
Total current assets	49,818	45,358
Property and equipment, net	749	929
Goodwill	6,399	6,399
Long-term restricted investments	150	150
Other long-term assets	282	277
Total assets	$57,398	$53,113
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$895	$1,520
Accrued liabilities	4,520	5,511
Contract research liabilities	710	834
Deferred revenue, current portion	203	682
Term loan, current portion, net	7,520	7,281
Total current liabilities	13,848	15,828
Deferred revenue, non-current portion	623	1,093
Term loan, non-current portion, net	12,341	12,634
Other long-term liabilities	2,317	2,070
Commitments and contingencies		
Stockholders' equity:		
Common stock	16	15
Additional paid-in capital	486,863	465,246
Accumulated other comprehensive loss	—	(1)
Accumulated deficit	(458,610)	(443,772)
Stockholders' equity	28,269	21,488
Total liabilities and stockholders' equity	$57,398	$53,113

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

DURECT CORPORATION

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share amounts)

(unaudited)

	Three months ended		Six months ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Collaborative research and development and other revenue	$645	$1,268	$1,741	$1,702
Product revenue, net	2,768	3,051	5,160	7,184
Total revenues	3,413	4,319	6,901	8,886
Operating expenses:				
Cost of product revenues	1,084	924	2,258	2,467
Research and development	6,120	9,079	13,072	16,627
Selling, general and administrative	2,816	3,681	6,010	6,724
Total operating expenses	10,020	13,684	21,340	25,818
Loss from operations	(6,607)	(9,365)	(14,439)	(16,932)
Other income (expense):				
Interest and other income	240	39	398	75
Interest expense	(644)	(601)	(1,267)	(1,184)
Net other expense	(404)	(562)	(869)	(1,109)
Net loss	$(7,011)	$(9,927)	$(15,308)	$(18,041)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	1	2	1	-
Total comprehensive loss	$(7,010)	$(9,925)	$(15,307)	$(18,041)
Net loss per share				
Basic	$(0.04)	$(0.07)	$(0.10)	$(0.13)
Diluted	$(0.04)	$(0.07)	$(0.10)	$(0.13)
Weighted-average shares used in computing net loss per share				
Basic	161,621	142,532	157,612	142,176
Diluted	161,621	142,532	157,612	142,176

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

DURECT CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six months ended June 30,	
	2018	2017
Cash flows from operating activities		
Net loss	$(15,308)	$(18,041)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	221	224
Stock-based compensation	1,300	1,228
Amortization of debt issuance cost	51	31
Net amortization (accretion) on investments	41	(65)
Changes in assets and liabilities:		
Accounts receivable	911	(231)
Inventories	(98)	68
Prepaid expenses and other assets	364	(1,013)
Accounts payable	(625)	(303)
Accrued and other liabilities	1,122	1,154
Contract research liabilities	(124)	1,348
Deferred revenue	(479)	18,977
Total adjustments	2,684	21,418
Net cash (used in) provided by operating activities	(12,624)	3,377
Cash flows from investing activities		
Purchases of property and equipment	(41)	(17)
Purchases of available-for-sale securities	(6,835)	-
Proceeds from maturities of available-for-sale securities	9,118	16,610
Net cash provided by investing activities	2,242	16,593
Cash flows from financing activities		
Payments on equipment financing obligations	(6)	(6)
Payment of additional issuance cost for term loan	(105)	-
Net proceeds from issuances of common stock	18,456	5,037
Net cash provided by financing activities	18,345	5,031
Net increase in Cash, cash equivalents, and restricted cash	7,963	25,001
Cash, cash equivalents, and restricted cash, beginning of the period	29,525	5,554
Cash, cash equivalents, and restricted cash, end of the period (1)	$37,488	$30,555
Supplementary disclosure of non-cash financing information		
Fully vested options issued to settle accrued liabilities	$1,860	$1,600

(1) Includes restricted cash of $150,000 (in long term restricted investments) included in the condensed balance sheets at both June 30, 2018 and June 30, 2017.

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

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 biopharmaceutical company with research and development programs broadly falling into two categories: (i) new chemical entities derived from our Epigenetics Regulator Program, in which we attempt to discover and develop molecules which have not previously been approved and marketed as therapeutics, and (ii) Drug Delivery Programs, in which we apply our formulation expertise and technologies largely to active pharmaceutical ingredients whose safety and efficacy have previously been established but which we aim to improve in some manner through a new formulation. 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, 2018, the operating results and comprehensive loss for the three and six months ended June 30, 2018 and 2017, and cash flows for the six months ended June 30, 2018 and 2017. The balance sheet as of December 31, 2017 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, 2017 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.

Liquidity and Need to Raise Additional Capital

As of June 30, 2018, the Company had an accumulated deficit of $458.6 million as well as negative cash flows from operating activities for the six months ended June 30, 2018.

The Company historically has had negative cash flows from operating activities and expects its negative cash flows to continue. The Company will continue to require substantial funds to continue research and development, including clinical trials of its product candidates. Management's plans in order to meet its operating cash flow requirements include seeking additional collaborative agreements for certain of its programs and achieving milestone and other payments under its collaboration and licensing agreements as well as financing activities such as public offerings and private placements of its common stock, preferred stock offerings, issuances of debt and convertible debt instruments.

There are no assurances that such additional funding will be obtained and that the Company will succeed in its future operations. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. Inventories, in part, include certain excipients that are sold to a customer for a currently marketed animal health product and included in several products in development or awaiting regulatory approval. These inventories are capitalized based on management's judgment of probable sale prior to their expiration dates. The valuation of inventory requires management to estimate the value of inventory that may become expired prior to use. The Company may be required to expense previously capitalized inventory costs upon a change in management's judgment due to, among other potential factors, a denial or delay of approval of a customer's product by the necessary regulatory bodies, or new information that suggests that the inventory will not be saleable. As of June 30, 2018, the remaining

carrying value of the excipient in the Company's inventory was $70,000. In the event that management determines that the Company will not utilize all of these materials, there could be a potential write-off related to this inventory. If the Company is able to subsequently sell products made with raw materials that were previously written down, the Company will report an unusually high gross profit as there will be no associated cost of goods for these materials.

The Company's inventories consist of the following (in thousands):

	June 30, 2018 (unaudited)	December 31, 2017
Raw materials	$ 247	$ 282
Work in process	1,401	1,182
Finished goods	1,615	1,699
Total inventories	$ 3,263	$ 3,163

Revenue Recognition

Effective January 1, 2018, the Company adopted FASB ASC Topic 606, Revenue from Contracts with Customers, or ASC 606. In accordance with ASC 606, the Company changed certain characteristics of its revenue recognition accounting policy as described below. ASC 606 was applied using the modified retrospective method, where the cumulative effect of the initial application was recognized as an adjustment to opening retained earnings at January 1, 2018. Therefore, comparative prior periods have not been adjusted and continue to be reported under FASB ASC Topic 605, Revenue Recognition, or ASC 605. The Company recorded a net increase to opening retained earnings of $470,000 with an offset entry to a contra liability account as of January 1, 2018 due to the cumulative impact of adopting Topic 606, with the impact relating to the Company's deferred collaborative research and development revenues. There was no impact to reported total assets, revenues and operating expenses for the three and six months ended June 30, 2018 as a result of applying Topic 606.

Product Revenue, Net

The Company 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.

Revenues from product sales are recognized when the customer obtains control of the Company's product, which occurs at a point in time, typically upon shipment to the customer. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that the Company would have recognized is one year or less.

Trade Discounts and Allowances: The Company provides certain customers with discounts that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Product Returns: Consistent with industry practice, the Company generally offers customers a limited right of return for products that have been purchased from the Company. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return liabilities using its own historical sales information. The Company expects product returns to be minimal.

Collaborative Research and Development Revenues

The Company enters into license agreements which are within the scope of Topic 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; reimbursement of development costs incurred by the Company under approved work plans; development, regulatory and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. Each of these payments results in collaborative research and development revenues, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;

(iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success. The Company expects to recognize revenue for the variable consideration currently being constrained when it is probable that a significant revenue reversal will not occur.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaborative research and development revenues and net income (loss) in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug product for either clinical development or commercial supply at the customer's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded in collaborative research and development revenue when the customer obtains control of the goods, which is upon delivery.

Royalties and Earn-outs: For arrangements that include sales-based royalties or earn-outs, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the

Company has not recognized any significant royalty revenue resulting from our collaborative arrangements or any earn-out revenue from our patent purchase agreement with Indivior.

The Company receives payments from its customers based on development cost schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Total revenue by geographic region for the three and six months ended June 30, 2018 and 2017 are as follows (in thousands):

	Three months ended		Six months ended	
	June 30,		June 30,	
	2018	2017	2018	2017
United States	$2,124	$2,273		