DURECT CORP
Form 10-Q
May 09, 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 March 31, 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 May 3, 2018, there were 161,709,306 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)

	March 31, 2018 (unaudited)	December 31, 2017 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$39,325	$29,375
Short-term investments	4,809	7,384
Accounts receivable (net of allowances of $191 at March 31, 2018 and $155 at December 31, 2017)	1,819	2,376
Inventories, net	3,254	3,163
Prepaid expenses and other current assets	2,801	3,060
Total current assets	52,008	45,358
Property and equipment, net	845	929
Goodwill	6,399	6,399
Long-term restricted investments	150	150
Other long-term assets	277	277
Total assets	$59,679	$53,113
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$791	$1,520
Accrued liabilities	4,923	5,511
Contract research liabilities	720	834
Deferred revenue, current portion	203	682
Term loan, current portion, net	4,655	7,281
Total current liabilities	11,292	15,828
Deferred revenue, non-current portion	623	1,093
Term loan, non-current portion, net	15,178	12,634
Other long-term liabilities	2,191	2,070
Commitments and contingencies		
Stockholders' equity:		
Common stock	16	15
Additional paid-in capital	481,979	465,246
Accumulated other comprehensive loss	(1)	(1)
Accumulated deficit	(451,599)	(443,772)
Stockholders' equity	30,395	21,488
Total liabilities and stockholders' equity	$59,679	$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 March 31,	
	2018	2017
Collaborative research and development and other revenue	$1,096	$434
Product revenue, net	2,392	4,133
Total revenues	3,488	4,567
Operating expenses:		
Cost of product revenues	1,174	1,543
Research and development	6,952	7,548
Selling, general and administrative	3,194	3,043
Total operating expenses	11,320	12,134
Loss from operations	(7,832)	(7,567)
Other income (expense):		
Interest and other income	158	36
Interest expense	(623)	(583)
Net other expense	(465)	(547)
Net loss	$(8,297)	$(8,114)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	-	(2)
Total comprehensive loss	$(8,297)	$(8,116)
Net loss per share		
Basic	$(0.05)	$(0.06)
Diluted	$(0.05)	$(0.06)
Weighted-average shares used in computing net loss per share		
Basic	153,558	141,815
Diluted	153,558	141,815

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

DURECT CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Three months ended March 31,	
	2018	2017
Cash flows from operating activities		
Net loss	$(8,297)	$(8,114)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	108	112
Stock-based compensation	661	665
Amortization of debt issuance cost	23	16
Net accretion/amortization on investments	16	(42)
Changes in assets and liabilities:		
Accounts receivable	557	(922)
Inventories	(89)	320
Prepaid expenses and other assets	259	(419)
Accounts payable	(729)	(948)
Accrued and other liabilities	1,396	220
Contract research liabilities	(114)	4
Deferred revenue	(479)	(9)
Total adjustments	1,609	(1,003)
Net cash used in operating activities	(6,688)	(9,117)
Cash flows from investing activities		
Purchases of property and equipment	(24)	(6)
Purchases of available-for-sale securities	(1,741)	-
Proceeds from maturities of available-for-sale securities	4,300	7,234
Net cash provided by investing activities	2,535	7,228
Cash flows from financing activities		
Payments on equipment financing obligations	(3)	(3)
Payment of additional issuance cost for term loan	(105)	-
Net proceeds from issuances of common stock	14,211	760
Net cash provided by financing activities	14,103	757
Net increase (decrease) in Cash, cash equivalents, and restricted cash	9,950	(1,132)
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)	$39,475	$4,422
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 March 31, 2018 and March 31, 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 March 31, 2018, the operating results and comprehensive loss for the three months ended March 31, 2018 and 2017, and cash flows for the three months ended March 31, 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 March 31, 2018, the Company had an accumulated deficit of $451.6 million as well as negative cash flows from operating activities.

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 March 31, 2018, the remaining

carrying value of the excipient in the Company's inventory was $68,000. 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):

	March 31, 2018 (unaudited)	December 31, 2017
Raw materials	$ 312	$ 282
Work in process	1,187	1,182
Finished goods	1,755	1,699
Total inventories	$ 3,254	$ 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 months ended March 31, 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.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts and returns that are offered within contracts between the Company and its customers relating to the Company's sales of its products.

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 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 months ended March 31, 2018 and 2017 are as follows (in thousands):

	Three months ended March 31,	
	2018	2017
United States	$2,234	$3,197
Europe	756	507
Japan	287	374
Other	211	489
Total	$3,488	$4,567

The cumulative effect of the changes made to our January 1, 2018 balance sheet for the adoption of ASC 606 Revenue – Revenue from Contract with Customers were as follows (in thousands):

	Balance at December 31, 2017	Adjustments Due to ASC606	Balance at January 1, 2018
Condensed Balance Sheets			
Liabilities			
Deferred revenue, non-current portion	$1,093	$ 470	$623
Equity			
Accumulated deficit	$(443,772)	$ 470	$(443,302)

During the three months ended March 31, 2018, the Company did not recognize any revenue as a result of changes in the contract asset and the contract liability balances associated with the Company's deferred research and development revenues for the Company's collaboration agreements as a result of adoption of ASC 606.

In accordance with the new revenue standard requirements, the disclosure of the impact of adoption on condensed balance sheets, condensed statements of comprehensive loss, and condensed statements of cash flows for the period ended March 31, 2018 was as follows (in thousands):

	As of March 31, 2018		
	As reported	Balances without adoption of ASC 606	Effect of change Higher/(Lower)
Condensed Balance Sheets			
Liabilities			
Deferred revenue, non-current portion	$623	$ 1,093	$ (470)

	For the three months ended March 31, 2018		
	As reported	Balances without adoption of ASC 606	Effect of change Higher/(Lower)
Condensed Statements of Comprehensive Loss			
Collaborative research and development and other revenue	$1,096	$ 1,096	$ -
Product revenue, net	2,392	2,392	-
Total revenues	$3,488	$ 3,488	$ -

	For the three months ended March 31, 2018		
	As reported	Balances without adoption of ASC 606	Effect of change Higher/(Lower)
Condensed Statements of Cash Flow			
Cash flow from Operating Activities			
Deferred revenue, non-current portion	$(479)	$ -	$ (479)

For the reporting periods before January 1, 2018, revenue was recognized under ASC 605, Revenue Recognition. For a detailed description for our revenue recognition policy prior to January 1, 2018, please see Note 1, “Revenue Recognition” to our audited condensed financial statements included in our annual report on Form 10-K for the year ended December 31, 2017.

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. Total comprehensive loss has been disclosed in the Company's Statements of Comprehensive Loss.

Net Income (Loss) Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding. Diluted net 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.

The numerators and denominators in the calculation of basic and diluted net loss per share were as follows (in thousands except per share amounts):

	Three months ended March 31,	
	2018	2017
Numerators:		
Net loss	(8,297)	(8,114)
Denominator:		
Weighted average shares used to compute basic net loss per share	153,558	141,815
Dilutive common shares from stock options and ESPP	-	-
Weighted average shares used to compute diluted net loss per share	153,558	141,815
Net loss per share:		
Basic	$(0.05)	$(0.06)
Diluted	$(0.05)	$(0.06)

Options to purchase 16.8 million and 26.3 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the three months ended March 31, 2018 and 2017, respectively, as the effect would be anti-dilutive.

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows (Topic 230): Restricted Cash." The FASB issued the update to clarify how restricted cash or restricted cash equivalents should be presented in the statement of cash flows. The standard will be effective for fiscal years beginning after December 15, 2017, including interim periods within those years, and the guidance will generally be applied retroactively. The Company has adopted the amendments provided in ASU 2016-18 in these condensed financial statements to provide financial statement users with more transparent disclosure about restricted cash and restricted cash equivalents. Upon adoption, the amendments provided in this update are applied using a retrospective transition method to each period presented. The cash, cash equivalents, restricted cash, and restricted cash equivalents balance included $150,000 of restricted cash and restricted cash equivalents as of both March 31, 2018 and March 31, 2017. Restricted cash and restricted cash equivalents are included in long-term restricted investments in the accompanying condensed balance sheets as of March 31, 2018 and December 31, 2017, respectively.

In March 2018, the FASB issued ASU 2018-05, "Income Taxes (Topic 740), Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118." The ASU adds various Securities and Exchange Commission ("SEC")

paragraphs pursuant to the issuance of the December 2017 SEC Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118"), which was effective immediately. The SEC issued SAB 118 to address concerns about reporting entities' ability to timely comply with the accounting requirements to recognize all of the effects of the Tax Cuts and Jobs Act in the period of enactment. SAB 118 allows disclosure that timely determination of some or all of the income tax effects from the Tax Cuts and Jobs Act are incomplete by the due date of the financial statements and if possible to provide a reasonable estimate. The Company has accounted for the tax effects of the Tax Cuts and Jobs Act under the guidance of SAB 118, on a provisional basis. The Company's accounting for certain income tax effects is incomplete, but the Company has determined reasonable estimates for those effects and has recorded provisional amounts in its condensed financial statements as of March 31, 2018 and December 31, 2017.

In May 2017, the FASB issued ASU 2017-09, “Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting.” The FASB issued the guidance to provide clarity as to when modification accounting should be applied when there is a change to the terms or conditions of a share-based payment award in order to prevent diversity in practice. The ASU requires modification accounting to be applied unless all of the following conditions exist: (1) the fair value (or calculated value or intrinsic value, if such measurement is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such measurement is used) of the original award before the original award is modified; if the modification does not affect any of the inputs to the valuation, the entity is not required to estimate the value immediately before and after the modification; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award before it was modified; and (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award before it was modified. The guidance will be applied prospectively for annual periods and interim periods beginning after December 15, 2017. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance did not have a material impact on its financial position, results of operations, and disclosures.

In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments.” The FASB issued the update to clarify how entities should classify certain cash receipts and cash payments on the statement of cash flows. The new guidance also clarifies how the predominance principle should be applied when cash receipts and cash payments have aspects of more than one class of cash flows. The standard will be effective for fiscal years beginning after December 15, 2017, including interim periods within those years, and the guidance will generally be applied retrospectively. The Company adopted this guidance effective January 1, 2018. The adoption of this guidance did not have a material impact on its financial position, results of operations, and disclosures.

In May 2014, the FASB issued ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)” and subsequently issued additional guidance that modified ASU 2014-09. ASU 2014-09 and the subsequent modifications are identified as “ASC 606”. ASC 606 replaces existing revenue recognition rules with a comprehensive revenue measurement and recognition standard and provides for expanded disclosure requirements. The update requires entities to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASC 606 applies to all contracts with customers except those that are within the scope of other topics in the FASB Accounting Standards Codification.

On January 1, 2018, the Company adopted ASC 606 using the modified retrospective method. The Company applied the standard to contracts that were not completed as of the adoption date. The Company recognized the cumulative effect of initially applying ASC 606 as an adjustment to the opening balance of retained earnings. As a result of the adoption of ASC 606, the Company changed its accounting policy for revenue recognition. Refer to “Revenue Recognition” section above for further information.

Recently Issued Accounting Standards

In February 2018, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2018-02, “Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income.” The FASB issued the update to provide amended guidance to “allow a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act.” Additionally, under the new guidance an entity will be required to provide certain disclosures regarding stranded tax effects. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those years, and the guidance may be applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the U.S. federal income tax rate in the Tax Cuts and Jobs Act is recognized. Early adoption is permitted. The Company is currently assessing the effect that the ASU will have on its financial position, results of operations, and disclosures.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842).” The FASB issued the update to require the recognition of lease assets and lease liabilities on the balance sheet of lessees. The standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within such fiscal years. The ASU requires a modified retrospective transition method with the option to elect a package of practical expedients. Early adoption is permitted. The Company expects adoption to increase the assets and liabilities recorded on its condensed balance sheet and increase the level of disclosures related to leases. The Company is currently assessing the effect that the ASU will have on its financial position, results of operations, and disclosures.

Note 2. Strategic Agreements

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

	Three months ended March 31,	
	2018	2017
Collaborator		
Santen Pharmaceutical Co. Ltd. (Santen) (1)	$1	$94
Zogenix, Inc. (Zogenix) (2)	-	44
Pain Therapeutics, Inc. (Pain Therapeutics)	-	24
Others (3)	1,095	272
Total collaborative research and development and other revenue	$1,096	$434

(1) Amounts related to ratable recognition of upfront fees were zero and $57,000 for the three months ended March 31, 2018 and 2017, respectively.
(2) Amounts related to ratable recognition of upfront fees were zero and $42,000 for the three months ended March 31, 2018 and 2017, respectively. In August 2017, the Company and Zogenix terminated the Development and License Agreement between us dated July 11, 2011 relating to the development and commercialization of Relday.
(3) Includes revenue recognized associated with the Company's feasibility agreements for the three months ended March 31 2018 and 2017.

Agreement with Sandoz AG

In May 2017, the Company and Sandoz AG ("Sandoz") entered into a license agreement to develop and market POSIMIR® (SABER®-bupivacaine) in the United States. Following expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR), the agreement became effective in June 2017. POSIMIR is the Company's investigational post-operative pain relief depot that utilizes the Company's patented SABER technology to deliver bupivacaine to provide up to three days of pain relief after surgery. The Company retains commercialization rights in the rest of the world. Under terms of the agreement, Sandoz made an upfront payment of $20 million, and the Company remains eligible for up to an additional $30 million in milestone payments based on successful development and regulatory milestones, and up to an additional $230 million in sales-based milestones. DURECT was responsible for the completion of the ongoing PERSIST Phase 3 clinical trial for POSIMIR as well as FDA interactions through potential approval. If approved, DURECT also has certain manufacturing obligations under this agreement. Sandoz will have exclusive commercialization rights in the United States upon regulatory approval with sole funding responsibility for commercialization activities. Sandoz will pay the Company a tiered double-digit royalty on product sales for a defined period, after which the license granted to Sandoz shall convert to a non-exclusive, fully paid, royalty-free, irrevocable and perpetual license. The term of the agreement shall be for the duration of Sandoz's obligation to pay royalties for product sales under the Agreement. The agreement provides each party with specified termination rights, including the right of Sandoz to terminate at will after a specified period and each party to terminate the agreement upon material breach of the agreement by the other party. The failure of the PERSIST trial for POSIMIR to achieve its primary endpoint gives Sandoz a right to terminate our agreement with them on thirty days' notice, in addition to the rights they have to terminate for convenience on six

months' notice. In May 2018, the Company and Sandoz entered into an amendment (the "Amendment") to the license agreement. Pursuant to the Amendment, the Company is eligible for up to $30 million in milestone payments based on NDA approval, and remains eligible for up to an additional $230 million in sales-based milestones. Pursuant to the Amendment, each party is also permitted to develop or commercialize competing products. The Amendment also includes modifications to the Company's development obligations and to both parties' termination provisions, including a right for the Company to terminate for convenience prior to NDA approval, and a new termination fee payable to the Company in the event that Sandoz terminates the agreement for convenience. Except as expressly set forth in the Amendment, the license agreement remains in full force and effect.

The Company evaluated the agreement under the accounting guidance for multiple element arrangements and identified three deliverables: the license to develop and market POSIMIR, the research and development services and the manufacturing services. Given that the delivery of the manufacturing services by the Company is dependent upon approval of POSIMIR by the FDA, and that the fee to be received by the Company for these services, should they be delivered, is consistent with their estimated selling price, the Company considers the manufacturing services to be a contingent deliverable and has excluded them from the initial measurement and allocation of the arrangement consideration. The Company evaluated the license deliverable and concluded that it did not have stand alone value separate from the research and development services and accordingly combined these deliverables into a single unit of accounting. The Company allocated the arrangement consideration, which consists of the $20.0 million upfront payment, to this single unit of accounting. As of December 31, 2017, all of the $20.0 million upfront fee had been recognized as revenue as the Company's contractual performance obligations had been fulfilled.

Total collaborative research and development revenue recognized by the Company for Sandoz was zero for both the three months ended March 31, 2018 and 2017. The cumulative aggregate payments received by the Company from Sandoz as of March 31, 2018 were $20.0 million under this agreement.

Patent Purchase Agreement with Indivior

On September 26, 2017, the Company entered into a Patent Purchase Agreement (the "Agreement") with Indivior UK Limited ("Indivior"). Pursuant to the Agreement, the Company has assigned to Indivior certain patents that may provide further intellectual property protection for RBP-7000, Indivior's investigational once-monthly injectable risperidone product for the treatment of schizophrenia. In consideration for such assignment, Indivior has made an upfront non-refundable payment to DURECT of $12.5 million, and has also agreed to make an additional $5.0 million payment to DURECT contingent upon the achievement of a regulatory milestone, as well as quarterly earn-out payments that are based on a single digit percentage of U.S. net sales for certain products covered by the assigned patent rights, including RBP-7000. The assigned patent rights include granted patents extending through at least 2026. DURECT also receives a non-exclusive right under the assigned patents to develop and commercialize certain risperidone-containing products and products that do not contain risperidone or buprenorphine. The agreement contains customary representations, warranties and indemnities of the parties. The Company received the payment of $12.5 million from Indivior in September 2017 and recognized the $12.5 million as revenue from sale of intellectual property rights in 2017 as the Company did not have any continuing obligations under the purchase agreement.

In October 2017, Indivior disclosed that it submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) on September 28, 2017 to seek marketing approval for RBP-7000. Indivior has stated that this NDA submission includes the results from a pivotal Phase 3 study assessing the efficacy and safety of RBP-7000 and an open-label, long-terms safety study. Indivior noted that in the pivotal randomized, double-blind, placebo-controlled study, RBP-7000 demonstrated statistically significant clinical improvement compared to placebo based on changes in mean Positive and Negative Syndrome Scale (PANSS) total and Clinical Global Impression-Severity of Illness (CGI-S) scores at 8 weeks. In December 2017, Indivior announced that the FDA had accepted the NDA for RBP-7000 and that the FDA had set a PDUFA target action date of July 28, 2018.

Agreement with Pain Therapeutics, Inc.

In December 2002, the Company entered into an exclusive agreement with Pain Therapeutics, Inc. (Pain Therapeutics) to develop and commercialize on a worldwide basis REMOXY ER and other oral sustained release, abuse deterrent opioid products incorporating four specified opioid drugs, using the ORADUR technology. This agreement currently covers only REMOXY ER.

Under the terms of this agreement, Pain Therapeutics paid the Company an upfront license fee of $1.0 million, with the potential for an additional $3.0 million in performance milestone payments based on the successful development and approval of REMOXY ER. Of these potential milestones, all $3.0 million are development-based milestones.

There are no sales-based milestones under the agreement. As of March 31, 2018, the Company had received $1.5 million in cumulative milestone payments.

In March 2016, Pain Therapeutics resubmitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA), and in September 2016, Pain Therapeutics received a Complete Response Letter from the FDA for REMOXY ER. Based on its review, the FDA has determined that the NDA cannot be approved in its present form and specifies additional actions and data that are needed for drug approval. In February 2018, Pain Therapeutics stated that they had resubmitted the REMOXY ER NDA. In March 2018, Pain Therapeutics announced that the NDA had been accepted by the FDA and that the FDA has set a PDUFA (Prescription Drug User Fee Act) target action date of August 7, 2018.

Total collaborative research and development revenue recognized for REMOXY-related work performed by the Company for Pain Therapeutics was zero and $24,000 for the three months ended March 31, 2018 and 2017, respectively. The cumulative aggregate payments received by the Company from Pain Therapeutics as of March 31, 2018 were $40.4 million under this agreement.

Agreement with Zogenix, Inc.

On July 11, 2011, the Company and Zogenix, Inc. (Zogenix) entered into a Development and License Agreement (the Zogenix Agreement). The Company and Zogenix had previously been working together under a feasibility agreement pursuant to which the Company's research and development costs were reimbursed by Zogenix. Under the Zogenix Agreement, Zogenix was responsible for the clinical development and commercialization of a proprietary, long-acting injectable formulation of risperidone using the Company's SABER controlled-release formulation technology potentially in combination with Zogenix's DosePro® needle-free, subcutaneous drug delivery system. DURECT was responsible for non-clinical, formulation and CMC development activities. The Company was to be reimbursed by Zogenix for its research and development efforts on the product. Zogenix paid a non-refundable upfront fee to the Company of $2.25 million in July 2011. The Company's research and development services were considered integral to utilizing the licensed intellectual property and, accordingly, the deliverable was accounted for as a single unit of accounting. The $2.25 million upfront fee had been recognized as collaborative research and development revenue ratably over the term of the Company's research and development involvement with Zogenix with respect to this product candidate.

The Company granted to Zogenix an exclusive worldwide license, with sub-license rights, to the Company's intellectual property rights related to the Company's proprietary polymeric and non-polymeric controlled-release formulation technology to make and have made, use, offer for sale, sell and import risperidone products, where risperidone is the sole active agent, for administration by injection in the treatment of schizophrenia, bipolar disorder or other psychiatric related disorders in humans. The Company retained the right to supply Zogenix's Phase 3 clinical trial and commercial product requirements on the terms set forth in the Zogenix Agreement. Zogenix was permitted to terminate the Zogenix Agreement without cause at any time upon prior written notice, and either party was permitted to terminate the Zogenix Agreement upon certain circumstances including written notice of a material uncured breach.

In August 2017, the Company and Zogenix terminated the Zogenix Agreement. Under the mutual termination agreement, Zogenix's development and commercialization rights are returned to the Company, and Zogenix will transfer to the Company all regulatory filings and development information related to Relday. As a result of the termination of the Zogenix agreement, the Company recognized revenue during the third quarter of 2017 for the remaining $750,000 of deferred revenue related to the upfront fee as the Company had no remaining performance obligations under the agreement; this recognition of revenue did not result in additional cash proceeds to the Company.

The following table provides a summary of collaborative research and development revenue recognized under the agreements with Zogenix (in thousands). The cumulative aggregate payments received by the Company as of March 31, 2018 were $20.1 million under these agreements.

	Three months ended	
	March 31, 2018	2017
Ratable recognition of upfront payment	$-	$ 42
Research and development expenses reimbursable by Zogenix	-	2
Total collaborative research and development revenue	$-	$ 44

Agreement with Santen Pharmaceutical Co., Ltd.

On December 11, 2014, the Company and Santen Pharmaceutical Co., Ltd. (Santen) entered into a definitive agreement (the Santen Agreement). Pursuant to the Santen Agreement, the Company granted Santen an exclusive worldwide license to the Company's proprietary SABER formulation platform and other intellectual property to develop and commercialize a sustained release product utilizing the Company's SABER technology to deliver an ophthalmology drug. Santen controls and funds the development and commercialization program, and the parties established a joint management committee to oversee, review and coordinate the development activities of the parties under the Santen Agreement.

In connection with the Santen agreement, Santen agreed to pay the Company an upfront fee of $2.0 million in cash and to make contingent cash payments to the Company of up to $76.0 million upon the achievement of certain milestones, of which $13.0 million are development-based milestones and $63.0 million are commercialization-based milestones including milestones requiring the achievement of certain product sales targets (none of which has been achieved as of March 31, 2018). Santen will also pay for certain Company costs incurred in the development of the licensed product. If the product is commercialized, the Company would also receive a tiered royalty on annual net product sales ranging from single-digit to the low double digits, determined on a country-by-country basis. As of March 31, 2018, the cumulative aggregate payments received by the Company under this agreement were $3.3 million.

The following table provides a summary of collaborative research and development revenue recognized under the Santen Agreement (in thousands).

	Three months ended March 31,	
	2018	2017
Ratable recognition of upfront payment	$-	$ 57
Research and development expenses reimbursable by Santen	1	37
Total collaborative research and development revenue	$1	$ 94

Note 3. Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company's valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The Company follows a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value. These levels of inputs are the following:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's financial instruments are valued using quoted prices in active markets or based upon other observable inputs. Money market funds are classified as Level 1 financial assets. Certificates of deposit, commercial paper, corporate debt securities, and U.S. Government agency securities are classified as Level 2 financial assets. The fair value of the Level 2 assets is estimated using pricing models using current observable market information for similar securities. The Company's Level 2 investments include U.S. government-backed securities and corporate securities that are valued based upon observable inputs that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. The fair value of commercial paper is based upon the time to maturity and discounted using the three-month treasury bill rate. The average remaining maturity of the Company's Level 2 investments as of March 31, 2018 is less than twelve months and these investments are rated by S&P and Moody's at AAA or AA- for securities and A1 or P1 for commercial paper.

The following is a summary of available-for-sale securities as of March 31, 2018 and December 31, 2017 (in thousands):

	March 31, 2018			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$870	$ -	$ -	$870
Certificates of deposit	150	-	-	150
Commercial paper	40,616	-	-	40,616
Corporate debt	1,616	-	(1)	1,615
	$43,252	$ -	$ (1)	$43,251
Reported as:				
Cash and cash equivalents	$38,292	$ -	$ -	$38,292
Short-term investments	4,810	-	(1)	4,809
Long-term restricted investments	150	-	-	150
	$43,252	$ -	$ (1)	$43,251

	December 31, 2017			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Money market funds	$568	$ -	$ -	$568
Certificates of deposit	150	-	-	150
Commercial paper	33,307	-	-	33,307
Corporate debt	1,298	-	(1)	1,297
	$35,323	$ -	$ (1)	$35,322
Reported as:				
Cash and cash equivalents	$27,788	$ -	$ -	$27,788
Short-term investments	7,385	-	(1)	7,384
Long-term restricted investments	150	-	-	150
	$35,323	$ -	$ (1)	$35,322

The following is a summary of the cost and estimated fair value of available-for-sale securities at March 31, 2018, by contractual maturity (in thousands):

	March 31, 2018	
	Amortized Cost	Estimated Fair Value
Mature in one year or less	$42,382	$42,381
	$42,382	$42,381

There were no securities that have had an unrealized loss for more than 12 months as of March 31, 2018.

As of March 31, 2018, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered to be temporary. The Company believes that it is more-likely-than-not that investments in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in market value.

Note 4. Stock-Based Compensation

As of March 31, 2018, the Company has three stock-based compensation plans. The stock-based compensation cost that has been included in the statements of comprehensive loss is shown as below (in thousands):

	Three months ended March 31,	
	2018	2017
Cost of product revenues	$25	$28
Research and development	353	369
Selling, general and administrative	283	268
Total stock-based compensation	$661	$665

As of March 31, 2018 and December 31, 2017, $14,000 of stock-based compensation cost was capitalized in inventory on the Company’s balance sheets.

The Company uses the Black-Scholes option pricing model to value its stock options. The expected life computation is based on historical exercise patterns and post-vesting termination behavior. The Company considered its historical volatility in developing its estimate of expected volatility.

The Company used the following assumptions to estimate the fair value of stock options granted and shares purchased under its employee stock purchase plan for the three months ended March 31, 2018 and 2017:

	Three months ended	
	March 31,	
	2018	2017
Stock Options		
Risk-free rate	2.7-2.9%	2.2-2.5%
Expected dividend yield	—	—
Expected life of option (in years)	7.0-10.0	6.08-10.0
Volatility	80-86%	75-82%

	Three months ended	
	March 31,	
	2017	2016
Employee Stock Purchase Plan		
Risk-free rate	1.3%	0.6%
Expected dividend yield	—	—
Expected life of option (in years)	0.5	0.5
Volatility	146%	81%

Note 5. Term Loan

In July 2016, the Company entered a $20.0 million secured single-draw term loan with Oxford Finance LLC (Oxford Finance). The 2016 Loan Agreement provides for interest only payments for the first 18 months, followed by consecutive monthly payments of principal and interest in arrears starting on March 1, 2018 and continuing through the maturity date of the term loan of August 1, 2020. The 2016 Loan Agreement also provides for a floating interest rate (7.95% initially and 8.87% as of December 31, 2017) based on an index rate plus a spread, a $150,000 facility fee that was paid at closing and an additional payment equal to 9.25% of the principal amount of the term loan, which is due when the term loan becomes due or upon the prepayment of the facility. If the Company elects to prepay the loan, there is also a prepayment fee between 1% and 3% of the principal amount of the term loan depending on the timing of prepayment. The facility fee and other debt offering/issuance costs have been recorded as debt discount on the Company’s balance sheet and together with the final $1.9 million payment are being amortized to interest expense during the life of the term loan using the effective interest rate method.

The term loan is secured by substantially all of the assets of the Company, except that the collateral does not include any intellectual property (including licensing, collaboration and similar agreements relating thereto), and certain other excluded assets. The 2016 Loan Agreement contains customary representations, warranties and covenants by the Company, which covenants limit the Company’s ability to convey, sell, lease, transfer, assign or otherwise dispose of certain assets of the Company; engage in any business other than the businesses currently engaged in by the Company or reasonably related thereto; liquidate or dissolve; make certain management changes; undergo certain change of control events; create, incur, assume, or be liable with respect to certain indebtedness; grant certain liens; pay

dividends and make certain other restricted payments; make certain investments; and make payments on any subordinated debt.

The 2016 Loan Agreement also contains customary indemnification obligations and customary events of default, including, among other things, the Company's failure to fulfill certain obligations of the Company under the 2016 Loan Agreement and the occurrence of a material adverse change which is defined as a material adverse change in the Company's business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan, or a material impairment in the perfection or priority of lender's lien in the collateral or in the value of such collateral. In the event of default by the Company under the 2016 Loan Agreement, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which the Company may be required to repay all amounts then outstanding under the 2016 Loan Agreement, which could harm the Company's financial condition. The conditionally exercisable call option related to the event of default is considered to be an embedded derivative which is required to be bifurcated and accounted for as a separate financial instrument. In the periods presented, the value of the embedded derivative is not material, but could become material in future periods if an event of default became more probable than is currently estimated.

In February 2018, the Company and Oxford Finance entered into a First Amendment of the Loan Agreement, which modified the terms of the Loan Agreement to change the first principal payment date from March 1, 2018 to December 1, 2018 and to increase the additional payment due when the term loan becomes due or upon the prepayment of the facility from 9.25% of the principal

amount of the term loan to 10% of such amount. The interest rate and the maturity date remain unchanged, and the Company paid Oxford Finance a loan modification fee of $100,000.

The fair value of the term loan approximates the carrying value. Future maturities and interest payments due under the term loan as of March 31, 2018, are as follows (in thousands):

Nine months ended December 31, 2018	$3,113
2019	12,463
2020	8,845
Total minimum payments	24,421
Less amount representing interest	(4,421)
Gross balance of term loan	20,000
Less unamortized debt discount	(167)
Carrying value of term loan	19,833
Less term loan, current portion, net	(4,655)
Term loan, non-current portion, net	$15,178

As of March 31, 2018, the Company was in compliance with all material covenants under the Loan Agreement and there had been no material adverse change.

Note 6. Stockholders' Equity

During the three months ended March 31, 2018, the Company raised net proceeds (net of commissions) of approximately $13.7 million from the sale of 8,171,275 shares of the Company's common stock in the open market at a weighted average price of $1.73 per share, through its Controlled Equity Offering sales agreement with Cantor Fitzgerald, entered into in November 2015 (Controlled Equity Offering).

Note 7. Subsequent Events

From April 1, 2018 to April 9, 2018, the Company raised net proceeds (net of commissions) of approximately $3.1 million from the sale of 1.5 million shares of the Company's common stock in the open market through the Controlled Equity Offering program with Cantor Fitzgerald at a weighted average price of $2.22 per share. No shares were sold under the Controlled Equity Offering program subsequent to April 9, 2018. As of May 3, 2018, the Company had up to approximately $514,000 of common stock available for sale under the Controlled Equity Offering program and approximately $67.8 million of common stock available for sale under its shelf registration statement.

Effective May 4, 2018, the Company and Sandoz entered into an amendment (the "Amendment") to the license agreement dated May 5, 2017, regarding POSIMIR in the United States. Pursuant to the Amendment, the Company is eligible for up to $30 million in milestone payments based on NDA approval, and remains eligible for up to an additional $230 million in sales-based milestones. Pursuant to the Amendment, each party is also permitted to develop or commercialize competing products. The Amendment also includes modifications to the Company's

development obligations and to both parties' termination provisions, including a right for the Company to terminate for convenience prior to NDA approval, and a new termination fee payable to the Company in the event that Sandoz terminates the agreement for convenience. Except as expressly set forth in the Amendment, the license agreement remains in full force and effect.

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, 2018 and 2017 should be read in conjunction with our annual report on Form 10-K for the year ended December 31, 2017 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, the words "believe," "anticipate," "intend," "plan," "estimate," "expect," "may," "will," "could," "po similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations and beliefs. 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.

Forward-looking statements made in this report include, for example, statements about:

- the clinical trial plans for DUR-928;
- potential regulatory filings for or approval of RBP-7000, REMOXY ER, DUR-928, POSIMIR, or any of our or any third parties' other product candidates;
- the progress of our third-party collaborations, including estimated milestones;
- our intention to seek, and ability to enter into and maintain strategic alliances and collaborations;
- the potential benefits and uses of our products;
- responsibilities of our third-party collaborators, including the responsibility to make cost reimbursement, milestone, royalty and other payments to us, and our expectations regarding our collaborators' plans with respect to our products and continued development of our products;
- our responsibilities to our third-party collaborators, including our responsibilities to conduct research and development, clinical trials and manufacture products;
- our ability to protect intellectual property, including intellectual property licensed to our collaborators;
- market opportunities for products in our product pipeline;
- the progress and results of our research and development programs and our evaluation of additional development programs;
    - requirements for us to purchase supplies and raw materials from third parties, and the ability of third parties to provide us with required supplies and raw materials;
- the results and timing of clinical trials, including for DUR-928, REMOXY ER and POSIMIR, the possible commencement of future clinical trials and announcements of the findings of our clinical trials;
- conditions for obtaining regulatory approval of our product candidates;
- submission and timing of applications for regulatory approval;
- the impact of FDA, DEA, EMEA and other government regulation on our business;
- the impact of potential Risk Evaluation and Mitigation Strategies (REMS) on our business;
- uncertainties associated with obtaining and protecting patents and other intellectual property rights, as well as avoiding the intellectual property rights of others;
- products and companies that will compete with the products we license to third-party collaborators;
- the possibility we may commercialize our own products and build up our commercial, sales and marketing capabilities and other required infrastructure;
- the possibility that we may develop additional manufacturing capabilities;
- our employees, including the number of employees and the continued services of key management, technical and scientific personnel;
- our future performance, including our anticipation that we will not derive meaningful revenues from our products in development for at least the next twelve months, potential for future inventory write-offs and our expectations regarding our ability to achieve profitability;

- sufficiency of our cash resources, anticipated capital requirements and capital expenditures, our ability to comply with covenants of our term loan, and our need for additional financing, including potential sales under our shelf registration statement;