DURECT CORP
Form 10-Q
November 08, 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 September 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 every Interactive Data File required to be submitted 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 such files). Yes No

Indicate by a check mark whether the registrant a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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 November 2, 2018, there were 162,059,718 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)

	September 30, 2018 (unaudited)	December 31, 2017 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,217	$ 29,375
Short-term investments	3,090	7,384
Accounts receivable (net of allowances of $68 at September 30, 2018 and $155 at December 31, 2017)	1,606	2,376
Inventories, net	3,485	3,163
Prepaid expenses and other current assets	2,870	3,060
Total current assets	49,268	45,358
Property and equipment, net	677	929
Goodwill	6,399	6,399
Long-term restricted investments	150	150
Other long-term assets	366	277
Total assets	$ 56,860	$ 53,113
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,152	$ 1,520
Accrued liabilities	5,200	5,511
Contract research liabilities	1,375	834
Deferred revenue, current portion	13	682
Term loan, current portion, net	10,390	7,281
Total current liabilities	18,130	15,828
Deferred revenue, non-current portion	812	1,093
Term loan, non-current portion, net	9,500	12,634
Other long-term liabilities	2,324	2,070
Commitments and contingencies		
Stockholders' equity:		
Common stock	16	15
Additional paid-in capital	487,403	465,246
Accumulated other comprehensive loss	—	(1)
Accumulated deficit	(461,325)	(443,772)
Stockholders' equity	26,094	21,488
Total liabilities and stockholders' equity	$ 56,860	$ 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		Nine months ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Collaborative research and development and other revenue	$5,691	$5,602	$7,432	$7,304
Product revenue, net	2,345	2,644	7,505	9,828
Revenue from sale of intellectual property rights	-	12,500	-	12,500
Total revenues	8,036	20,746	14,937	29,632
Operating expenses:				
Cost of product revenues	912	3,105	3,170	5,572
Research and development	6,542	8,378	19,614	25,005
Selling, general and administrative	2,870	3,138	8,880	9,862
Total operating expenses	10,324	14,621	31,664	40,439
Income (Loss) from operations	(2,288)	6,125	(16,727)	(10,807)
Other income (expense):				
Interest and other income	234	605	632	680
Interest expense	(661)	(619)	(1,928)	(1,803)
Net other expense	(427)	(14)	(1,296)	(1,123)
Net income (loss)	$(2,715)	$6,111	$(18,023)	$(11,930)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	-	3	1	3
Total comprehensive income (loss)	$(2,715)	$6,114	$(18,022)	$(11,927)
Net income (loss) per share				
Basic	$(0.02)	$0.04	$(0.11)	$(0.08)
Diluted	$(0.02)	$0.04	$(0.11)	$(0.08)
Weighted-average shares used in computing net income (loss) per share				
Basic	162,002	147,213	159,091	143,873
Diluted	162,002	151,885	159,091	143,873

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

DURECT CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine months ended September 30,	
	2018	2017
Cash flows from operating activities		
Net loss	$(18,023)	$(11,930)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Sale of intellectual property rights for non-operating purposes	-	(500)
Depreciation and amortization	162	333
Stock-based compensation	1,839	1,929
Inventory write-down	228	2,176
Amortization of debt issuance cost	80	46
Net amortization (accretion) on investments	70	(61)
Changes in assets and liabilities:		
Accounts receivable	770	(1,026)
Inventories	(547)	(50)
Prepaid expenses and other assets	101	(937)
Accounts payable	(368)	(28)
Accrued and other liabilities	1,975	1,897
Contract research liabilities	541	(55)
Deferred revenue	(479)	14,295
Total adjustments	4,372	18,019
Net cash (used in) provided by operating activities	(13,651)	6,089
Cash flows from investing activities		
Sale of intellectual property rights for non-operating purposes	-	500
Purchases of property and equipment	(73)	(81)
Purchases of available-for-sale securities	(6,893)	(5,248)
Proceeds from maturities of available-for-sale securities	11,118	18,533
Net cash provided by investing activities	4,152	13,704
Cash flows from financing activities		
Payments on equipment financing obligations	(10)	(10)
Payment of additional issuance cost for term loan	(105)	-
Net proceeds from issuances of common stock	18,456	10,100
Net cash provided by financing activities	18,341	10,090
Net increase in Cash, cash equivalents, and restricted cash	8,842	29,883
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)	$38,367	$35,437
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 September 30, 2018 and September 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 the Company's Epigenetics Regulator Program, in which the Company attempts to discover and develop molecules which have not previously been approved and marketed as therapeutics, and (ii) Drug Delivery Programs, in which the Company applies its formulation expertise and technologies largely to active pharmaceutical ingredients whose safety and efficacy have previously been established but which the Company aims 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 September 30, 2018, the operating results and comprehensive loss for the three and nine months ended September 30, 2018 and 2017, and cash flows for the nine months ended September 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 September 30, 2018, the Company had an accumulated deficit of $461.3 million as well as negative cash flows from operating activities for the nine months ended September 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 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. 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):

	September 30, 2018 (unaudited)	December 31, 2017
Raw materials	$ 256	$ 282
Work in process	1,540	1,182
Finished goods	1,689	1,699
Total inventories	$ 3,485	$ 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 nine months ended September 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. The Company earned a $5.0 million milestone payment from Indivior UK Limited ("Indivior") upon NDA approval of PERSERIS in the three months ended September 30, 2018.

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 the Company's collaborative arrangements or any earn-out revenue from the Company’s 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 nine months ended September 30, 2018 and 2017 are as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
United States	$1,931	$3,243	$6,129	$8,609
Europe	5,585	16,812	7,088	18,490
Japan	149	317	722	1,097
Other	371	374	998	1,436
Total	$8,036	$20,746	$14,937	$29,632

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

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

During the three and nine months ended September 30, 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 September 30, 2018 was as follows (in thousands):

	As of September 30, 2018		
	As reported	Balances without adoption of ASC 606	Effect of change Higher/(Lower)
Condensed Balance Sheets			
Liabilities			
Deferred revenue, non-current portion	$812	$1,282	$ (470)

	For the nine months ended September 30, 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	$7,432	$7,432	$ -
Product revenue, net	7,505	7,505	-
Total revenues	$14,937	$14,937	$ -

	For the nine months ended September 30, 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 the Company's revenue recognition policy prior to January 1, 2018, please see Note 1, "Revenue Recognition" to the Company's audited financial statements included in its 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 presented 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		Nine months ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Numerators:				
Net income (loss)	(2,715)	6,111	(18,023)	(11,930)
Denominator:				
Weighted average shares used to compute basic net income (loss) per share	162,002	147,213	159,091	143,873
Dilutive common shares from stock options and ESPP	-	4,672	-	-
Weighted average shares used to compute diluted net income (loss) per share	162,002	151,885	159,091	143,873
Net income (loss) per share:				
Basic	$(0.02)	$0.04	$(0.11)	$(0.08)
Diluted	$(0.02)	$0.04	$(0.11)	$(0.08)

Options to purchase approximately 17.2 million and 15.6 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the three and nine months ended September 30, 2018, respectively, as the effect would be anti-dilutive. Options to purchase approximately 20.0 million shares of common stock were excluded from the denominator in the calculation of diluted net loss per share for the nine months ended September 30, 2017, as the effect would be anti-dilutive.

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 September 30, 2018 and December 31, 2017. Restricted cash and restricted cash equivalents are included in long-term restricted investments in the accompanying condensed balance sheets as of September 30, 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 September 30, 2018 and December 31, 2017.

Recently Issued Accounting Standards

In August 2018, the FASB issued Accounting Standards Update ("ASU") No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. This standard is effective for fiscal years beginning after December 15, 2019, including interim reporting periods within those years, with early adoption permitted. The Company does not expect the adoption of this standard to have a material effect on its financial statements.

In June 2018, the FASB issued Accounting Standards Update ("ASU") No. 2018-07, Compensation – Stock Compensation (Topic 718), which expands the scope of ASC 718 to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. Under the new standard, most of the guidance on stock compensation payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. This standard is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within those years, with early adoption permitted. The Company does not expect the adoption of this standard to have a material effect on its financial statements.

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 does not expect the adoption of this standard to have a material effect on its financial statements.

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 has identified the major leasing arrangements for which transition adjustments will be recorded and the package of practical expedients which will be elected. In addition, the Company anticipates recognition of additional assets and corresponding liabilities related to leases on the Company's Condensed Balance Sheets upon adoption of the ASU.

Note 2. Strategic Agreements

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Collaborator/Counterparty				