INTERCEPT PHARMACEUTICALS INC
Form 10-Q
November 06, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2017

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: 001-35668

INTERCEPT PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**22-3868459**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
10 Hudson Yards, 37th FL New York, NY	**10001**
(Address of Principal Executive Offices)	**(Zip Code)**

(646) 747-1000

(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 x 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 x No ¨

Indicate by check mark whether the registrant is 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 x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	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 x

As of September 30, 2017, there were 25,102,079 shares of common stock, $0.001 par value per share, outstanding.

Intercept Pharmaceuticals, Inc.

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Unless the context otherwise indicates, references in this Quarterly Report on Form 10-Q to “we,” “our,” “us” and “the Company” refer, collectively, to Intercept Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “w “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the potential benefit and commercial potential of Ocaliva® (obeticholic acid, or OCA) in primary biliary cholangitis, or PBC, and our ability to maintain our regulatory approval of Ocaliva in PBC in the United States, Europe and other jurisdictions in which we have or may receive marketing authorization;
- the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;
- the timing of and our ability to obtain regulatory approval of OCA in indications other than PBC and regulatory approval of any other product candidates which we may develop;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our products and product candidates, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), and any related restrictions, limitations and/or warnings in the label of any products or product candidates;
- our plans to research, develop and commercialize our products and product candidates;
- our ability to obtain and maintain intellectual property protection for our products and product candidates;
- our ability to successfully commercialize our products and product candidates;
- the size and growth of the markets for our products and product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any products, which may be affected by the reimbursement received from payors;
- the success of competing drugs that are or become available;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers;
- our collaborators’ election to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our need for and ability to obtain additional financing;
- our estimates regarding expenses, revenues and capital requirements and the accuracy thereof;
- our use of cash and short-term investments; and
- our ability to attract and retain key scientific or management personnel.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2017, particularly in Item 1.A. Risk Factors, and in our subsequent periodic and current reports filed with the Securities and Exchange Commission, including those filed in this Quarterly Report on Form 10-Q. Those risk factors, together with any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to the Quarterly Report on Form 10-Q with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

NON-GAAP FINANCIAL MEASURES

This Quarterly Report on Form 10-Q presents projected adjusted operating expense, which is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP, and should be considered in addition to, but not as a substitute for, operating expense that we prepare and announce in accordance with GAAP. We exclude certain items from adjusted operating expense, such as stock-based compensation and other non-cash items, that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. For the nine months ended September 30, 2016, adjusted operating expense also excludes a one-time $45 million net expense for the settlement of a purported class action lawsuit. Other than the net class action lawsuit settlement amount, which is a one-time expense, we anticipate that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under GAAP. A reconciliation of projected non-GAAP adjusted operating expense to operating expense calculated in accordance with GAAP is not available on a forward-looking basis without unreasonable effort due to an inability to make accurate projections and estimates related to certain information needed to calculate, for example, future stock-based compensation expense. Management also uses adjusted operating expense to establish budgets and operational goals and to manage our company’s business. Other companies may define this measure in different ways. We believe this presentation provides investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

NOTE REGARDING TRADEMARKS

The Intercept Pharmaceuticals® name and logo and the Ocaliva® name and logo are either registered or unregistered trademarks or trade names of Intercept Pharmaceuticals, Inc. in the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I

Item 1. FINANCIAL STATEMENTS

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets

(In thousands, except per share data)

	September 30, 2017 (Unaudited)	December 31, 2016 (Audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 120,244	$ 43,675
Investment securities, available-for-sale	372,506	645,710
Accounts receivable, net	14,487	9,126
Prepaid expenses and other current assets	14,278	9,354
Total current assets	521,515	707,865
Fixed assets, net	18,141	11,295
Inventory, net	3,897	2,279
Security deposits	16,873	17,814
Total assets	$ 560,426	$ 739,253
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$ 82,070	$ 65,551
Short-term interest payable	3,737	7,267
Short-term portion of deferred revenue	1,782	5,694
Total current liabilities	87,589	78,512
Long-term liabilities:		
Long-term debt	351,984	341,356
Long-term other liabilities	6,068	-
Long-term portion of deferred revenue	3,118	4,453
Total liabilities	448,759	424,321
Stockholders' equity:		
Preferred stock par value $0.001 per share; 5,000,000 shares authorized; none outstanding as of September 30, 2017 and December 31, 2016, respectively	-	-
Common stock par value $0.001 per share; 45,000,000 shares authorized; 25,102,079 and 24,819,918 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	25	25
Additional paid-in capital	1,470,545	1,426,168
Accumulated other comprehensive loss, net	(632)	(2,801)

Accumulated deficit	(1,358,271)	(1,108,460)
Total stockholders' equity	111,667	314,932
Total liabilities and stockholders' equity	$ 560,426	$ 739,253

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations

(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue:				
Product revenue, net	$40,889	$4,732	$91,933	$4,807
Licensing revenue	445	445	1,336	6,336
Total revenue	41,334	5,177	93,269	11,143
Operating expenses:				
Cost of sales	172	-	548	-
Selling, general and administrative	61,356	52,802	189,363	197,382
Research and development	45,977	35,411	134,001	102,292
Total operating expenses	107,505	88,213	323,912	299,674
Operating loss	(66,171)	(83,036)	(230,643)	(288,531)
Other income (expense):				
Interest expense	(7,354)	(7,065)	(21,840)	(7,065)
Other income, net	924	1,286	3,388	2,807
	(6,430)	(5,779)	(18,452)	(4,258)
Net loss	$(72,601)	$(88,815)	$(249,095)	$(292,789)
Net loss per common and potential common share:				
Basic and diluted	$(2.89)	$(3.59)	$(9.96)	$(11.90)
Weighted average common and potential common shares outstanding:				
Basic and diluted	25,104	24,738	25,021	24,614

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net loss	$(72,601)	$(88,815)	$(249,095)	$(292,789)
Other comprehensive loss:				
Unrealized gains (losses) on securities:				
Unrealized holding gains (losses) arising during the period	409	(1,073)	1,114	966
Reclassification for recognized losses on marketable investment securities during the period	-	-	-	(52)
Net unrealized gains (losses) on marketable investment securities	$409	$(1,073)	$1,114	$914
Foreign currency translation adjustments	488	(691)	1,055	(1,585)
Comprehensive loss	$(71,704)	$(90,579)	$(246,926)	$(293,460)

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$ (249,095)	$ (292,789)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	41,584	27,041
Amortization of investment premium	2,777	3,736
Amortization of deferred financing costs	1,052	326
Depreciation	3,256	2,187
Accretion of debt discount	9,576	3,001
Realized gain on investments	-	52
Changes in operating assets:		
Prepaid expenses and other current assets	(4,924)	(984)
Accounts receivable	(5,361)	-
Inventory	(1,618)	-
Security deposits	-	(1,803)
Changes in operating liabilities:		
Accounts payable, accrued expenses and other current liabilities	16,519	1,699
Long-term other liabilities	6,068	-
Interest payable	(3,530)	3,738
Deferred revenue	(5,247)	817
Net cash used in operating activities	(188,943)	(252,979)
Cash flows from investing activities:		
Purchases of investment securities	(127,002)	(443,323)
Refund of security deposits	941	-
Sales of investment securities	398,543	361,019
Purchases of equipment, leasehold improvements, and furniture and fixtures	(10,102)	(4,005)
Net cash provided by (used in) investing activities	262,380	(86,309)
Cash flows from financing activities:		
Payments for capped call transactions and associated costs	-	(38,364)
Proceeds from issuance of Convertible Notes, net of issuance costs	-	447,715
Proceeds from exercise of options, net	2,077	4,429
Net cash provided by financing activities	2,077	413,780
Effect of exchange rate changes	1,055	(2,018)
Net increase in cash and cash equivalents	76,569	72,474
Cash and cash equivalents – beginning of period	43,675	32,742
Cash and cash equivalents – end of period	$ 120,244	$ 105,216

See accompanying notes to the condensed consolidated financial statements.

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INTERCEPT PHARMACEUTICALS, INC.
Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Overview of Business

Intercept Pharmaceuticals, Inc. (“Intercept” or the “Company”) is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases, including primary biliary cholangitis (“PBC”), nonalcoholic steatohepatitis (“NASH”), primary sclerosing cholangitis (“PSC”) and biliary atresia. Founded in 2002 in New York, Intercept now has operations in the United States, Europe and Canada.

2. Basis of Presentation

The Company’s financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”). All intercompany accounts and transactions have been eliminated. Certain information that is normally required by U.S. GAAP has been condensed or omitted in accordance with rules and regulations of the Securities and Exchange Commission (“SEC”). Operating results for the three and nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2017. In the opinion of management, these unaudited condensed consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim unaudited condensed consolidated financial statements.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2016, included in the Company’s 2016 Annual Report on Form 10-K filed with the SEC.

Certain reclassifications have been made to prior period amounts in the Company’s unaudited condensed consolidated statements of operations to conform to the current period presentation. The Company reclassified certain medical affairs costs of $8.4 million and $20.3 million from research and development expense to selling, general and administrative expense on the unaudited condensed consolidated statements of operations during the three and nine months ended September 30, 2016.

Use of Estimates

The preparation of these unaudited consolidated condensed financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, revenues and related disclosures. Significant estimates include: clinical trial accruals, revenues and share-based compensation expense. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

3. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 3 of Notes to Consolidated Financial Statements included in its Annual Report on Form 10-K for the year ended December 31, 2016.

Revenue Recognition

Product Revenue, Net

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. When the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue on the balance sheet until such time that all criteria are met.

The Company commenced its commercial launch of Ocaliva® (obeticholic acid or "OCA") for the treatment of PBC in the United States in June 2016. In December 2016, the European Commission granted conditional approval for the treatment of PBC and the Company commenced launch in January of 2017. In May 2017, Health Canada granted a conditional approval for the treatment of PBC and the Company commenced launch in July of 2017. The Company sells Ocaliva to a limited number of specialty pharmacies which dispense the product directly to patients. The specialty pharmacies are referred to as the Company's customers.

The Company provides the right of return to its customers for unopened product for a limited time before and after its expiration date. Prior to July 2017, given the Company's limited sales history for Ocaliva and the inherent uncertainties in estimating product returns, the Company determined that the shipments of Ocaliva made to its customers did not meet the criteria for revenue recognition at the time of shipment. Accordingly, the Company recognized revenue when the product was sold through by its customers, provided all other revenue recognition criteria were met. The Company invoiced its customers upon shipment of Ocaliva to them and recorded accounts receivable, with a corresponding liability for deferred revenue equal to the gross invoice price. The Company then recognized revenue when Ocaliva was sold through as specialty pharmacies dispensed product directly to the patients (sell-through basis).

The Company re-evaluated its revenue recognition policy in the third quarter of 2017, which included the accumulation and review of customer related transactions since the Company's commercial launch in the second quarter of 2016. The Company now believes it has accumulated sufficient data to reasonably estimate product returns and, therefore, it will now effectively recognize revenue at the time of shipment to its customers (sell-in basis).

During the third quarter of 2017, the Company recorded an adjustment related to this change in estimate to recognize previously deferred revenue. The net effect was an increase in net sales of Ocaliva of $4.1 million for the three and nine months ended September 30, 2017. The Company also established a new reserve of $0.7 million during the third quarter of 2017 related to future returns from its customers under its various contracts.

The Company recognized net sales of Ocaliva of $40.9 million and $4.7 million for the three months ended September 30, 2017 and 2016, respectively, and $91.9 million and $4.8 million for the nine months ended September 30, 2017 and 2016, respectively.

The Company has written contracts with each of its customers and delivery occurs when the customer receives Ocaliva. The Company evaluates the creditworthiness of each of its customers to determine whether collection is reasonably assured. In order to conclude that the price is fixed and determinable, the Company must be able to (i) calculate its gross product revenues from the sales to its customers and (ii) reasonably estimate its net product revenues. The Company calculates gross product revenues based on the wholesale acquisition cost that the Company charges its customers for Ocaliva. The Company estimates its net product revenues by deducting from its gross product revenues (i) trade allowances, such as invoice discounts for prompt payment and customer fees, (ii) estimated government rebates and discounts related to Medicare, Medicaid and other government programs, and (iii) estimated costs of incentives offered to certain indirect customers including patients.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements of FASB ASC Topic 605,

Revenue Recognition and most industry-specific guidance throughout the ASC, resulting in the creation of FASB ASC Topic 606, Revenue from Contracts with Customers. ASU 2014-09 requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. This ASU provides alternative methods of adoption. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers, Deferral of the Effective Date ("ASU 2015-14"). ASU 2015-14 defers the effective date of ASU 2014-09 by one year to December 15, 2017 for fiscal years, and interim periods within those years, beginning after that date and permits early adoption of the standard, but not before the original effective date for fiscal years beginning after December 15, 2016. In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers, Principal versus Agent Considerations (Reporting Revenue Gross versus Net) ("ASU 2016-08") clarifying the implementation guidance on principal versus agent considerations. Specifically, an entity is required to determine whether the nature of a promise is to provide the specified good or service itself (that is, the entity is a principal) or to arrange for the good or service to be provided to the customer by the other party (that is, the entity is an agent). The determination influences the timing and amount of revenue recognition. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing, clarifying the implementation guidance on identifying performance obligations and licensing. Specifically, the amendments reduce the cost and complexity of identifying promised goods or services and improves the guidance for determining whether promises are separately identifiable. The amendments also provide implementation guidance on determining whether an entity's promise to grant a license provides a customer with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time). The effective date and transition requirements for ASU 2016-08 and ASU 2016-10 are the same as the effective date and transition requirements for ASU 2014-09. The Company is currently evaluating which transition approach it will utilize and the impact of adopting ASU 2014-09, ASU 2016-08 and ASU 2016-10 on its consolidated financial statements and related disclosures. The Company continues to execute on its implementation plan for ASC 606 and its assessment of the impact that adoption will have on the Company's consolidated financial statements; specifically, as it relates to different revenue streams within a given contract and the impact adoption of ASC 606 could have on the Company's financial statement disclosures. The Company will adopt Topic 606 in the first quarter of 2018 using the modified retrospective method which consists of applying and recognizing the cumulative effect of Topic 606 at the date of initial application and providing certain additional disclosures as defined per Topic 606. The Company is in the process of reviewing variable consideration, potential disclosures, and our method of adoption to complete our evaluation of the impact on our consolidated financial statements prior to the end of 2017. In addition, we continue to monitor additional changes, modifications, clarifications or interpretations undertaken by the FASB, which may impact our current conclusions.

On August 27, 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"), which requires an entity to evaluate whether conditions or events, in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern for one year from the date the financial statements are issued or are available to be issued. The guidance became effective January 1, 2017. The Company adopted ASU No. 2014-15 on January 1, 2017, and its adoption did not have a material impact on the Company's financial statements.

In January 2016, FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2016-01 will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02") which supersedes Topic 840, Leases. ASU 2016-02 requires lessees to recognize a right-of-use asset and a lease liability on their balance sheets for all the leases with terms greater than twelve months. Based on certain criteria, leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. For leases with a term of twelve months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients primarily focused on leases that commenced before the effective date of Topic 842, including continuing to account for leases that commence before the effective date in accordance with previous guidance, unless the lease is modified. The Company is evaluating the impact of the adoption of the standard on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09") which is intended to improve the accounting for share-based payment transactions as part of the FASB's simplification initiative. The ASU changes certain aspects of the accounting for share-based payment award transactions, including: (1) accounting for income taxes; (2) classification of excess tax benefits on the statement of

cash flows; (3) forfeitures; (4) minimum statutory tax withholding requirements; and (5) classification of employee taxes paid on the statement of cash flows when an employer withholds shares for tax withholding purposes. The ASU is effective for fiscal years beginning after December 15, 2016, and interim periods within those years for public business entities. The Company adopted ASU 2016-09 during the first quarter of 2017. In connection with the adoption of this ASU, the Company elected to account for forfeitures as they occur and applied this change in accounting policy on a modified retrospective basis. As a result, the Company recorded a cumulative-effect adjustment to retained earnings which resulted in an increase to accumulated deficit of $0.7 million with an offsetting increase to additional paid-in capital (zero net total equity impact) as of the date of adoption, related to additional stock compensation expense that would have been recognized on unvested outstanding options unadjusted for estimated forfeitures. As a result of this guidance, the Company also recorded $58.7 million of additional deferred tax assets, which are fully offset by a valuation allowance. Other provisions of ASU 2016-09 had no impact on the Company’s consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. It is effective prospectively for the annual period ending December 31, 2018 and interim periods within that annual period. Early adoption is permitted. The Company is evaluating the impact of adoption of the standard on the consolidated financial statements and related disclosures, but does not expect it to have a significant impact.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception, (ASU 2017-11). Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its financial statements and related disclosures, but does not expect it to have a significant impact.

4. Significant Agreements

Sumitomo Dainippon Pharma Co, Ltd. (Sumitomo Dainippon)

In March 2011, the Company entered into an exclusive license agreement with Sumitomo Dainippon to research, develop and commercialize OCA as a therapeutic for the treatment of PBC and NASH in Japan and China (excluding Taiwan). Under the terms of the license agreement, the Company received an up-front payment from Sumitomo Dainippon of $15.0 million and may be eligible to receive additional milestone payments of up to an aggregate of approximately $30.0 million in development milestones based on the initiation or completion of clinical trials, $70.0 million in regulatory approval milestones and $200.0 million in sales milestones. The regulatory approval milestones include $15.0 million for receiving marketing approval of OCA for NASH in Japan, $10.0 million for receiving marketing approval of OCA for NASH in China, and $5.0 million for receiving marketing approval of OCA for PBC in the United States, which was achieved upon the FDA approval of Ocaliva for the treatment of PBC in May 2016. As of September 30, 2017, the Company had achieved $6.0 million of the development milestones under its collaboration agreement with Sumitomo Dainippon. The sales milestones are based on aggregate sales amounts of OCA in the Sumitomo Dainippon territory and include $5.0 million for achieving net sales of $50.0 million, $10.0 million for achieving net sales of $100.0 million, $20.0 million for achieving net sales of $200.0 million, $40.0 million for achieving net sales of $400.0 million and $120.0 million for achieving net sales of $1.2 billion. The Company has determined that each potential future development, regulatory and sales milestone is substantive. In May 2014, Sumitomo Dainippon exercised its option under the license agreement to add Korea as part of its licensed territories and paid the Company a $1.0 million up-front fee. Sumitomo Dainippon has the option to add several other Asian countries to its territory to pursue OCA for additional indications. Sumitomo Dainippon will be responsible for the costs of developing and commercializing OCA in its territories. Sumitomo Dainippon is also required to make royalty payments ranging from the tens to the twenties in percent based on net sales of OCA products in the Sumitomo Dainippon territory.

The Company evaluated the license agreement with Sumitomo Dainippon and determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under this license include an exclusive license to its technology, technical and scientific support to the development plan and participation on a joint steering committee. The Company determined that these performance obligations represent a single unit of accounting, since, initially, the license does not have stand-alone value to Sumitomo Dainippon without the Company's technical expertise and steering committee participation during the development of OCA. This development period is currently estimated as continuing through June 2020 and, as such, the up-front payment and payments made in respect of the Korea option are being recognized ratably over this period. During the three months ended September 30, 2017 and 2016, the Company recorded licensing revenue of approximately $0.4 million and $0.4 million, respectively. During the nine months ended September 30, 2017 and 2016, the Company recorded licensing revenue of approximately $1.3 million and $6.3 million, respectively.

5. Cash, Cash Equivalents and Investments

The following table summarizes the Company's cash, cash equivalents and investments as of September 30, 2017 and December 31, 2016:

	As of September 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$120,244	$ -	$ -	$120,244
Investment securities:				
Commercial paper	11,468	-	(4)	11,464
Corporate debt securities	342,252	1	(433)	341,820
U.S. government and agency securities	19,248	-	(26)	19,222
Total investments	372,968	1	(463)	372,506
Total cash, cash equivalents and investments	$493,212	$ 1	$ (463)	$492,750

	As of December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$43,675	$ -	$ -	$43,675
Investment securities:				
Commercial paper	66,185	-	(71)	66,114
Corporate debt securities	554,847	14	(1,443)	553,418
U.S. government and agency securities	26,254	-	(76)	26,178
Total investments	647,286	14	(1,590)	645,710
Total cash, cash equivalents and investments	$690,961	$ 14	$ (1,590)	$689,385

As of September 30, 2017, the Company held a total of forty eight positions that were in a continuous unrealized loss position for more than twelve months. The Company has determined that the unrealized losses are deemed to be temporary impairments as of September 30, 2017. The Company believes that the unrealized losses generally are caused by increases in the risk premiums required by market participants rather than an adverse change in cash flows or a fundamental weakness in the credit quality of the issuer or underlying assets. Because the Company has the ability and intent to hold these investments until a recovery of fair value, which may be maturity, it does not consider the investments to be other-than-temporarily impaired at September 30, 2017.

6. Fixed Assets, Net

Fixed assets are stated at cost and depreciated or amortized using the straight-line method based on useful lives as follows:

	Useful lives (Years)	September 30, 2017	December 31, 2016
		(In thousands)	
Office equipment and software	3	$ 5,044	$ 4,942
Leasehold improvements	Over life of lease	15,280	6,668
Furniture and fixtures	7	5,250	4,202
Subtotal		25,574	15,812
Less: accumulated depreciation		(7,433)	(4,517)
Fixed assets, net		$ 18,141	$ 11,295

7. Inventory, Net

Inventories are stated at the lower of cost or market. Inventories consist of the following:

	September 30, 2017	December 31, 2016
	(In thousands)	
Work-in-process	$ 3,717	$ 2,207
Finished goods	180	72
Inventory, net	$ 3,897	$ 2,279

8. Accounts Payable, Accrued Expenses and Other Liabilities

Accounts payable, accrued expenses and other liabilities consisted of the following:

	September 30, 2017	December 31, 2016
	(In thousands)	
Accounts payable	$ 10,053	$ 6,722
Accrued contracted services	44,244	35,429
Accrued employee compensation	18,720	19,287
Other liabilities	9,053	4,113
Accounts payable, accrued expenses and other liabilities	$ 82,070	$ 65,551

9. Fair Value Measurements

The carrying amounts of the Company’s receivables and payables approximate their fair value due to their short maturities.

Accounting principles provide guidance for using fair value to measure assets and liabilities. The guidance includes a three-level hierarchy of valuation techniques used to measure fair value, defined as follows:

- Unadjusted Quoted Prices — The fair value of an asset or liability is based on unadjusted quoted prices in active markets for identical assets or liabilities (Level 1).

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- Pricing Models with Significant Observable Inputs — The fair value of an asset or liability is based on information derived from either an active market quoted price, which may require further adjustment based on the attributes of the financial asset or liability being measured, or an inactive market transaction (Level 2).
- Pricing Models with Significant Unobservable Inputs — The fair value of an asset or liability is primarily based on internally derived assumptions surrounding the timing and amount of expected cash flows for the financial instrument. Therefore, these assumptions are unobservable in either an active or inactive market (Level 3).

The Company considers an active market as one in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. Conversely, the Company views an inactive market as one in which there are few transactions for the asset or liability, the prices are not current, or price quotations vary substantially either over time or among market makers. Where appropriate, non-performance risk, or that of a counterparty, is considered in determining the fair values of liabilities and assets, respectively.

The Company’s cash deposits and money market funds are classified within Level 1 of the fair value hierarchy because they are valued using bank balances or quoted market prices. Investments are classified as Level 2 instruments based on market pricing and other observable inputs.

Financial assets carried at fair value are classified in the tables below in one of the three categories described above:

		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
	(In thousands)			
September 30, 2017				
Assets:				
Money market funds (included in cash and cash equivalents)	$37,426	$ 37,426	$ -	$ -
Available for sale securities:				
Commercial paper	11,464	-	11,464	-
Corporate debt securities	341,820	-	341,820	-
U.S. government and agency securities	19,222	-	19,222	-
Total financial assets:	$409,932	$ 37,426	$ 372,506	$ -
December 31, 2016				
Assets:				
Money market funds (included in cash and cash equivalents)	$11,755	$ 11,755	$ -	$ -
Available for sale securities:				
Commercial paper	66,114	-	66,114	-
Corporate debt securities	553,418	-	553,418	-
U.S. government and agency securities	26,178	-	26,178	-
Total financial assets	$657,465	$ 11,755	$ 645,710	$ -

The estimated fair value of marketable debt securities (commercial paper, corporate debt securities and U.S. government and agency securities), by contractual maturity, are as follows:

	Fair Value as of	
	September 30, 2017	December 31, 2016
	(In thousands)	
Due in one year or less	$344,852	$ 456,184
Due after 1 year through 5 years	27,654	189,526
Total investments in debt securities	$372,506	$ 645,710

Actual maturities may differ from contractual maturities because issuers may have the right to call or prepay obligations without call or prepayment penalties.

10. Long-Term Debt

Debt, net of discounts and deferred financing costs, consists of the following:

	September 30, 2017	December 31, 2016
	(In thousands)	
Long-term debt	$351,984	$ 341,356
Less current portion	-	-
Long-term debt outstanding	$351,984	$ 341,356

On July 6, 2016, the Company issued $460.0 million aggregate principal amount of the 3.25% convertible senior notes due 2023 (“Convertible Notes”). The Company received net proceeds of $447.6 million after deducting underwriting discounts and estimated offering expenses of approximately $12.4 million. The Company used approximately $38.4 million of the net proceeds from the offering to fund the payment of the cost of the capped call transactions that were entered into in connection with the issuance of the Convertible Notes.

The Convertible Notes are senior unsecured obligations of the Company. Interest is payable semi-annually on January 1 and July 1 of each year, beginning on January 1, 2017. The Convertible Notes mature on July 1, 2023, unless earlier repurchased, redeemed or converted. The Convertible Notes are convertible at the option of holders, under certain circumstances and during certain periods, into cash, shares of the Company’s common stock or a combination of cash and shares of the Company’s common stock, at the Company’s election. The initial conversion rate of the Convertible Notes is 5.0358 shares of the Company’s common stock per $1,000 principal amount of Convertible Notes, which is equivalent to an initial conversion price of approximately $198.58 per share of the Company’s common stock. The conversion rate is subject to adjustment upon the occurrence of certain events. The Company may redeem for cash all or part of the Convertible Notes, at its option, on or after July 6, 2021, under certain circumstances at a redemption price equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

The capped call transactions are expected generally to reduce the potential dilution upon conversion of the Convertible Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Convertible Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Convertible Notes. The cap price of the capped call transactions is initially $262.2725 per share, and is subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, exceeds the cap price of the capped call transactions, there would nevertheless be dilution upon conversion of the Convertible Notes to the extent that such market price exceeds the cap price of the capped call transactions.

In accordance with ASC Subtopic 470-20, the Company used an effective interest rate of 8.4% to determine the liability component of the Convertible Notes. This resulted in the recognition of $334.4 million as the liability component of the Convertible Notes and the recognition of the residual $113.2 million as the debt discount with a corresponding increase to additional paid-in capital for the equity component of the Convertible Notes.

Interest expense was $7.4 million and $7.1 million for the three months ended September 30, 2017 and 2016, respectively, and $21.8 million and $7.1 million for the nine months ended September 30, 2017 and 2016, respectively, related to the Convertible Notes. Accrued interest on the Convertible Notes was approximately $3.7 million and $7.3 million as of September 30, 2017 and December 31, 2016, respectively. The Company recorded debt issuance costs of $12.4 million, which are being amortized using the effective interest method. As of September 30, 2017, $10.7 million of debt issuance costs are recorded on the unaudited condensed consolidated balance sheet in Long-Term Debt, in accordance with ASU 2015-03. As of September 30, 2017, the Company had outstanding borrowings of $460.0 million related to the Convertible Notes.

11. Product Revenue, Net

The Company recognized net sales of Ocaliva of $40.9 million and $4.7 million for the three months ended September 30, 2017 and 2016, respectively, and $91.9 million and $4.8 million for the nine months ended September 30, 2017 and 2016, respectively.

The table below summarizes consolidated product revenue, net by region:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
(In thousands)				

Product revenue, net:				
U.S.	$36,176	$4,732	$ 83,829	$ 4,807
ex-U.S.	4,713	-	8,104	-
Total product revenue, net	$40,889	$4,732	$ 91,933	$ 4,807

12. Stock Compensation

The 2012 Equity Incentive Plan ("2012 Plan") became effective upon the pricing of the initial public offering in October 2012. At the same time, the 2003 Stock Incentive Plan ("2003 Plan") was terminated and 555,843 shares available under the 2003 Plan were added to the 2012 Plan.

On January 1, 2017, the number of shares reserved for issuance under the 2012 Plan was increased by 993,558 shares, as a result of the automatic increase in shares reserved pursuant to the terms thereof.

The estimated fair value of the options that have been granted under the 2003 and 2012 Plans is determined utilizing the Black-Scholes option-pricing model at the date of grant. The fair value of restricted stock units ("RSUs") and restricted stock awards ("RSAs") that have been granted under the 2012 Plan is determined utilizing the closing stock price on the date of grant.

The following table summarizes stock option activity during the nine months ended September 30, 2017:

	Number of Shares (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (In thousands)
Outstanding at December 31, 2016	1,553	$ 117.80	7.4	$ 48,308
Granted	499	$ 113.27	-	$ -
Exercised	(85)	$ 24.36	-	$ -
Cancelled/forfeited	(103)	$ 141.78	-	$ -
Expired	(53)	$ 214.69	-	$ -
Outstanding at September 30, 2017	1,811	$ 116.76	7.3	$ 15,118
Expected to vest	1,811	$ 116.76	7.3	$ 15,118
Exercisable	914	$ 102.08	6.0	$ 15,115

As of September 30, 2017, there was approximately $54.2 million of total unrecognized compensation expense related to the unvested stock options shown in the table above, which is expected to be recognized over a weighted average period of 2.5 years.

The fair value of the Company's option awards were estimated using the assumptions below:

	Nine Months Ended September 30,	
	2017	**2016**
Volatility	60.9 - 65.4%	59.6 - 65.6%
Expected term (in years)	6.0 - 9.9	6.0 - 10.0
Risk-free rate	1.8 - 2.4%	1.1 - 1.8%
Expected dividend yield	—%	—%

The following table summarizes the aggregate RSU and RSA activity during the nine months ended September 30, 2017:

	Number of Awards **(In thousands)**	Weighted Average Fair Value
Non-vested shares outstanding, December 31, 2016	381	$ 136.89
Granted	262	$ 113.41

Vested	(133)	$ 135.92
Forfeited	(46)	$ 134.77
Non-vested shares outstanding, September 30, 2017	464	$ 124.11

As of September 30, 2017, there was approximately $46.9 million of total unrecognized compensation expense related to unvested RSUs and RSAs, which is expected to be recognized over a weighted average period of 2.6 years.

The Company accounts for forfeitures when they occur. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest. When performance based grants are issued, the Company recognizes no expense until achievement of the performance requirement is deemed probable.

Stock-based compensation expense has been reported in our statements of operations as follows:

	Three Months Ended September 30,	Nine Months Ended September 30,