INTERCEPT PHARMACEUTICALS INC
Form 10-Q
August 09, 2016

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 June 30, 2016

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)**
450 West 15th Street, Suite 505 New York, NY	**10011**
(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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting 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	¨

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 July 31, 2016, there were 24,726,376 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,” “potential,” “will,” “wou “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:

- our ability to successfully commercialize 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;
- the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;
- the timing of and our ability to obtain and maintain regulatory approval of OCA in PBC in countries outside the United States and in indications other than PBC and any other product candidates we may develop such as INT-767;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our 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 approved product candidates;
- our plans to research, develop and commercialize our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to successfully commercialize OCA in indications other than PBC and our other product candidates;
- the size and growth of the markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products, which may be affected by the reimbursement that our products receive from payors;
- the success of competing drugs that are or become available;
- the election by our collaborators to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers;
- our need for and ability to obtain additional financing;
- our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof;
- our use of our 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 February 29, 2016, 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 the anticipated $45 million net expense for the settlement of the purported securities class action lawsuit, 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. 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.

PART I

Item 1. FINANCIAL STATEMENTS

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

	June 30, 2016 (Unaudited)	December 31, 2015 (Audited)
	(In thousands)	
Assets		
Current assets:		
Cash and cash equivalents	$51,701	$ 32,742
Restricted cash	45,000	-
Investment securities, available-for-sale	387,786	595,313
Prepaid expenses and other current assets	20,781	13,638
Total current assets	505,267	641,693
Fixed assets, net	12,530	10,047
Security deposits	6,377	4,018
Total assets	$524,174	$ 655,758
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$42,693	$ 45,591
Litigation settlement	55,000	-
Short-term portion of deferred revenue	4,462	1,782
Total current liabilities	102,155	47,373
Long-term liabilities:		
Long-term portion of deferred revenue	5,345	6,236
Total liabilities	107,500	53,609
Stockholders' equity:		
Common stock 35,000,000 shares authorized; 24,675,929, and 24,391,430 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively; par value $0.001 per share	25	24
Additional paid-in capital	1,317,412	1,300,008
Accumulated other comprehensive income (loss), net	(1,160)	(2,253)
Accumulated deficit	(899,603)	(695,630)
Total stockholders' equity	416,674	602,149
Total liabilities and stockholders' equity	$524,174	$ 655,758

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands, except share and per share amounts)			
Revenue:				
Product revenue, net	$75	$-	$75	$-
Licensing revenue	5,445	445	5,891	1,891
Total revenue	5,520	445	5,966	1,891
Costs and expenses:				
Research and development	41,340	28,295	78,753	56,260
General and administrative	42,275	20,974	132,707	34,112
Total costs and expenses	83,615	49,269	211,460	90,372
Other income (expense):				
Other income, net	796	930	1,521	1,201
	796	$930	1,521	1,201
Net loss	$(77,299)	$(47,894)	$(203,973)	$(87,280)
Net loss per share:				
Basic and diluted	$(3.14)	$(1.99)	$(8.31)	$(3.78)
Weighted average shares outstanding:				
Basic and diluted	24,611,631	24,014,092	24,553,239	23,100,222

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)			
Net loss	$(77,299)	$(47,894)	$(203,973)	$(87,280)
Other comprehensive loss:				
Unrealized gains (losses) on securities:				
Unrealized holding gains (losses) arising during the period	305	(895)	2,038	(682)
Reclassification for recognized gains (losses) on marketable investment securities during the period	29	-	(51)	2
Net unrealized gains (losses) on marketable investment securities	$334	$(895)	$1,987	$(680)
Foreign currency translation adjustments	(368)	338	(894)	176
Comprehensive loss	$(77,333)	$(48,451)	$(202,881)	$(87,784)

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2016	2015
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (203,973)	$ (87,280)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	14,497	16,369
Depreciation	1,544	646
Amortization of investment premium	2,664	2,595
Changes in:		
Prepaid expenses, other current assets and security deposits	(9,501)	(3,581)
Accounts payable, accrued expenses and other current liabilities	(2,898)	8,547
Litigation settlement	55,000	-
Deferred revenue	1,790	(891)
Net cash used in operating activities	(140,877)	(63,595)
Cash flows from investing activities:		
Purchases of investment securities	(35,318)	(524,054)
Sales of investment securities	242,117	96,418
Litigation settlement (Restricted cash)	(45,000)	-
Purchases of equipment, leasehold improvements, and furniture and fixtures	(4,187)	(4,177)
Net cash provided by (used in) investing activities	157,612	(431,813)
Cash flows from financing activities:		
Proceeds from issuance of stock offerings, net of issuance costs	-	558,930
Proceeds from exercise of options	2,906	4,536
Net cash provided by financing activities	2,906	563,466
Effect of exchange rate changes	(682)	176
Net increase in cash and cash equivalents	18,959	68,234
Cash and cash equivalents – beginning of period	32,742	20,023
Cash and cash equivalents – end of period	$ 51,701	$ 88,257

See accompanying notes to the condensed consolidated financial statements.

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. The Company’s product candidates have the potential to treat orphan and more prevalent liver diseases for which there currently are limited therapeutic solutions. Intercept was incorporated in Delaware in September 2002.

The Company has its principal executive offices in New York, New York. The Company also has administrative offices in San Diego, California and London, United Kingdom.

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). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Use of Estimates

The preparation of these 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. On an ongoing basis, management evaluates estimates, clinical trial accruals 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.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 3 to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

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.

Beginning in June 2016, subsequent to the U.S. Food and Drug Administration (FDA) approval of Ocaliva® (obeticholic acid) for the treatment of primary biliary cirrhosis (PBC) in May 2016, the Company sells Ocaliva in the United States principally 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. Given the Company's limited sales history for Ocaliva and the inherent uncertainties in estimating product returns, the Company has determined that the shipments of Ocaliva made to its customers thus far do not meet the criteria for revenue recognition at the time of shipment. Accordingly, the Company recognizes revenue when the product is sold through by its customers, provided all other revenue recognition criteria are met. The Company invoices its customers upon shipment of Ocaliva to them and records accounts receivable, with a corresponding liability for deferred revenue equal to the gross invoice price. The Company then recognizes revenue when Ocaliva is sold through as specialty pharmacies dispense product directly to the patients.

The Company recognized net sales of Ocaliva for the second quarter 2016 of $75 thousand pursuant to the product launch in June 2016. The Company also recorded $2.7 million in deferred revenues on its balance sheet, which represents product shipped to distributors, but not sold through as of June 30, 2016.

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.

Trade Allowances

The Company provides invoice discounts on Ocaliva sales to certain of its customers for prompt payment and pays fees for certain distribution services, such as fees for certain data that its customers provide to the Company. The Company deducts the full amount of these discounts and fees from its gross product revenues at the time such discounts and fees are earned by such customers.

Rebates and Discounts

The Company contracts with Centers for Medicare & Medicaid Services (CMS) and other government agencies to make Ocaliva available to eligible patients. As a result, the Company estimates any rebates and discounts and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company's estimates of rebates and discounts are based on the government mandated discounts, which are statutorily-defined and applicable to these government funded programs. Government rebates that are invoiced directly to the Company are recorded in accrued liabilities on the condensed consolidated balance sheet. Gross-to-net adjustments were insignificant for the period ended June 30, 2016.

Other Incentives

Other incentives that the Company offers to indirect customers include co-pay assistance cards provided by the Company for PBC patients whom reside in states that permit co-pay assistance programs. The Company's co-pay assistance program is intended to reduce each participating patient's portion of the financial responsibility for Ocaliva purchase price to a specified dollar amount. The Company records each period the amount of co-pay assistance provided to eligible patients based on the terms of the program when product is dispensed by the specialty pharmacies to the patients.

3. 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 obeticholic acid (OCA) as a therapeutic for the treatment of primary biliary cirrhosis,

recently renamed primary biliary cholangitis (PBC) and nonalcoholic steatohepatitis (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 recently achieved upon the FDA approval of Ocaliva for the treatment of PBC in May 2016. As of June 30, 2016, 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 June 30, 2016 and 2015, the Company recorded licensing revenue of approximately $5.4 million and $0.4 million, respectively, and during the six months ended June 30 2016 and 2015, the Company recorded revenue of approximately $5.9 million and $1.9 million, respectively.

Leases

In January 2016, Intercept Pharma Europe Ltd. (IPEL), a wholly owned subsidiary of the Company, entered into an underlease with Performing Right Society, Ltd., for additional office space in the King's Cross area of London, United Kingdom. The Company is the guarantor to the underlease. The underlease provides IPEL with an additional 8,549 square feet of space. The lease term is anticipated to end in May 2024. The annual rent is approximately £726,665 (or approximately $1.0 million), payable quarterly. IPEL is also required to pay value added tax (VAT) on the rent. IPEL will be responsible for a portion of the insurance, certain service charges and taxes for the building based on the floor area rented by them. As security for the underlease, IPEL has provided the landlord with a rent deposit in an amount equal to twelve months' rent, plus applicable VAT. The underlease is subject to an "upwards only" open market rent review of the market rent with review to take place in June 2019.

In February 2016, the Company entered into a sublease with Restoration Hardware, Inc. for additional office space in New York City. The sublease provides the Company with an additional 10,785 square feet of space. The lease term is anticipated to end in February 2021. The annual rent is approximately $1.0 million payable monthly. The Company is also responsible for its proportionate share of increases in operating expenses beginning January 2017 as well as its proportionate share of increases in real estate taxes over the average of the 2015/2016 and 2016/2017 fiscal years. As security for the sublease, the Company delivered a letter of credit in the amount of approximately $0.3 million in favor of the sublandlord.

Security for these leases is included on the condensed consolidated balance sheets in "Security Deposits."

4. Investments

The following table summarizes the Company's cash, cash equivalents and investments as of June 30, 2016 and December 31, 2015:

	As of June 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized **Losses**	**Fair Value**
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$51,701	$ -	$ -	$ 51,701
Investment securities:				
Commercial paper	1,999	-	-	1,999

U.S. government and agency securities	41,841	21	(3)	41,859
Corporate debt securities	343,861	217	(150)	343,928
Total investments	387,701	238	(153)	387,786
Total cash, cash equivalents and investments	$439,402	$ 238	$ (153)	$ 439,487

	As of December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	**Fair Value**
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$32,742	$ -	$ -	$ 32,742
Investment securities:				
Commercial paper	1,993	-	(3)	1,990
U.S. government and agency securities	65,854	1	(182)	65,673
Corporate debt securities	529,368	2	(1,720)	527,650
Total investments	597,215	3	(1,905)	595,313
Total cash, cash equivalents and investments	$629,957	$ 3	$ (1,905)	$ 628,055

As of June 30, 2016, there were no marketable securities in a continuous unrealized loss position for more than twelve months.

5. Income Taxes

For the six months ended June 30, 2016 and 2015, no income tax expense or benefit was recognized. The Company's deferred tax assets are comprised primarily of net operating loss carryforwards (NOLs). The Company maintains a full valuation allowance on its deferred tax assets since it has not yet achieved sustained profitable operations. As a result, the Company has not recorded any income tax benefit since its inception.

As of June 30, 2016 and December 31, 2015, the Company had NOLs for U.S. federal income tax purposes of $472.5 million and $454.4 million, respectively, which expire between 2024 and 2036. The Company also has certain state and foreign NOLs in varying amounts depending on the different state and foreign tax laws. The U.S. federal NOLs include approximately $158.1 million and $151.0 million, respectively, of excess tax benefits related to stock-based payments that are not recognized as a deferred tax asset. The benefit of these deductions will be recognized through additional paid-in capital at the time the tax deduction results in a reduction of current taxes payable.

The Company's ability to utilize its NOLs may be limited under Section 382 of the Internal Revenue Code due to previous ownership changes. Although the Company believes that these ownership changes have not resulted in material limitations on its ability to use these NOLs, its ability to utilize these NOLs may be limited due to future ownership changes or for other reasons. Additionally, tax laws limit the time during which NOLs and certain other tax attributes may be utilized against future taxes. As a result, the Company may not be able to take full advantage of its carryforwards for federal, state, and foreign tax purposes.

6. 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).
- 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. When 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 or other observable inputs. None of the Company’s investments are classified within Level 3 of the fair value hierarchy.

Financial assets and liabilities, 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)			
June 30, 2016				
Assets:				
Money market funds	$12,500	$ 12,500	$ -	$ -
Available for sale securities:				-
Commercial paper	1,999	-	1,999	$ -
Corporate debt securities	41,859	-	41,859	-
U.S. government and agency securities	343,928	-	343,928	-
Total financial assets:	$400,286	$ 12,500	$ 387,786	$ -
December 31, 2015				
Assets:				
Money market funds	$4,826	$ 4,826	$ -	$ -
Available for sale securities:				
Commercial paper	1,990	-	1,990	-
Corporate debt securities	527,650	-	527,650	-
U.S. government and agency securities	65,673	-	65,673	-
Total financial assets	$600,139	$ 4,826	$ 595,313	$ -

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	
	June 30, 2016	December 31, 2015
	(In thousands)	
Due in one year or less	$300,527	$ 343,758
Due after 1 year through 2 years	87,259	251,555
Total investments in debt securities	$387,786	$ 595,313

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

Common Stock

As of June 30, 2016 and December 31, 2015, the Company had 35,000,000 authorized shares of common stock, $0.001 par value per share. At the 2016 annual meeting of stockholders held on July 19, 2016, the Company's stockholders approved an amendment to the Company's restated certificate of incorporation, as amended, to increase the number of authorized shares of common stock from 35,000,000 shares to 45,000,000 shares.

In February 2015, the Company completed a public offering of 1,150,000 shares of its common stock pursuant to a registration statement on Form S-3. After underwriting discounts and commissions and offering expenses, the Company received net proceeds of approximately $191.6 million.

In April 2015, the Company completed a public offering of 1,330,865 shares of its common stock pursuant to a registration statement on Form S-3. After underwriting discounts and commissions and offering expenses, the Company received net proceeds of approximately $367.1 million.

7. Stock-Based Compensation

The 2012 Equity Incentive Plan (2012 Plan) became effective upon the pricing of the IPO 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.

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 six months ended June 30, 2016:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2015	1,348,000	$ 108.49
Granted	392,415	$ 105.41
Exercised	(79,179)	$ 36.71
Expired	(4,119)	128.3
Forfeited	(17,126)	$ 156.92
Outstanding, June 30, 2016	1,639,991	$ 110.66
Exercisable, June 30, 2016	747,123	$ 71.49

The following table summarizes the aggregate RSU and RSA activity during the six months ended June 30, 2016:

	Number of Shares	Weighted Average Fair Value	Aggregate Intrinsic Value (In thousands)
Non-vested shares outstanding, December 31, 2015	193,164	$ 183.19	$ 28,849
Granted	244,694	$ 109.60	$ 34,913
Exercised	(47,004)	$ 145.28	$ (6,707)
Forfeited	(8,199)	$ 185.98	$ (1,170)
Non-vested shares outstanding, June 30, 2016	382,655	$ 140.73	$ 54,597

As of June 30, 2016, there was $47.6 million of unrecognized compensation expense related to unvested RSUs and RSAs, which is expected to be recognized over a weighted average of 2.82 years.

The following table summarizes additional information about unvested RSUs and RSAs outstanding:

	Number of Shares	Price	Intrinsic Value (In thousands)
Employees and directors	379,105	$142.68	$ 54,091
Consultants	3,550	$142.68	506
Outstanding at June 30, 2016	382,655		$ 54,597

8. Net Loss Per Share

The following table presents the historical computation of basic and diluted net loss per share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands, except share and per share amounts)			
Historical net loss per share				
Numerator:				
Net loss attributable to common stockholders	$(77,299)	$(47,894)	$(203,973)	$(87,280)
Denominator:				
Weighted average shares used in calculating net loss per share - basic and diluted	24,611,631	24,014,092	24,553,239	23,100,222
Net loss per share:				
Basic and diluted	$(3.14)	$(1.99)	$(8.31)	$(3.78)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)			
Options	1,640	1,232	1,640	1,232

Restricted stock units	383	37	383	37
Total	2,023	1,269	2,023	1,269

9. Recent Accounting Pronouncements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842) ("ASU 2016-2")* 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 2016-2 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.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting,* 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 is evaluating the impact of the adoption of the standard on its consolidated financial statements.

In April 2016, the FASB issued ASU 2016-10, *Revenue From Contracts With Customers* (Topic 606), which covers principal versus agent considerations. The core principle of the guidance in Topic 606 is that an entity should recognize revenue to depict the transfer of 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. The amendments in the update do not change the core principle of the guidance. The amendments clarify the implementation guidance on principal versus agent considerations. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements of update 2014-09, accounting standards update 2015-14 *Revenue From Contracts with Customers* (Topic 606). The effective date of update 2014-09 was deferred by one year. The Company is evaluating the impact of the adoption of the standard on its consolidated financial statements.

10. Litigation

On February 21, 2014 and February 28, 2014, purported shareholder class actions, styled *Scot H. Atwood v. Intercept Pharmaceuticals, Inc. et al.* and *George Burton v. Intercept Pharmaceuticals, Inc. et al.*, respectively, were filed in the United States District Court for the Southern District of New York, naming the Company and certain of its officers as defendants. These lawsuits were filed by stockholders who claim to be suing on behalf of anyone who purchased or otherwise acquired the Company's securities between January 9, 2014 and January 10, 2014.

The lawsuits alleged that the Company made material misrepresentations and/or omissions of material fact in its public disclosures during the period from January 9, 2014 to January 10, 2014, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to the Company's January 9, 2014 announcement that the FLINT trial had been stopped early based on a pre-defined interim efficacy analysis. Specifically, the lawsuits claimed that the January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo.

On April 22, 2014, two individuals each moved to consolidate the cases and a lead plaintiff was subsequently appointed by the Court. On June 27, 2014, the lead plaintiff filed an amended complaint on behalf of the putative class as contemplated by the order of the Court. The lead plaintiff was seeking unspecified monetary damages on behalf of

the putative class and an award of costs and expenses, including attorneys' fees. On August 14, 2014, the defendants filed a motion to dismiss the complaint. Oral arguments on the motion to dismiss were held on February 24, 2015. On March 4, 2015, the defendants' motion to dismiss was denied by the Court. The defendants answered the amended complaint on April 13, 2015. On July 15, 2015, the plaintiff moved for class certification and appointment of class representatives and class counsel. On September 14, 2015, the defendants opposed the plaintiff's class certification motion. The plaintiff filed its reply to the defendants' opposition on October 14, 2015, to which the defendants filed a sur-reply on November 10, 2015. Oral arguments on the class certification motion were held on January 20, 2016.

On May 2, 2016, the defendants reached an agreement with the lead plaintiff to seek Court approval of a proposed resolution. The plaintiffs moved for preliminary approval of the proposed settlement on May 5, 2016. On May 23, 2016, the Court entered an order preliminarily approving the settlement. The Court ordered that notice be provided to the class and preliminarily approved the proposed settlement, including the payment of $55 million, of which $10 million was agreed to be funded by the Company's insurers. The settlement was paid into escrow in June 2016, with distribution to the class to occur after the Court has finally approved the settlement and a plan of allocation of those proceeds. The Court has scheduled a hearing to consider final approval of the proposed settlement on September 8, 2016. The $45 million held in escrow pending the final approval of the settlement by the Court is accounted for as restricted cash and as an accrued liability on the Company's June 30, 2016 consolidated balance sheet.

Under the proposed settlement, the defendants do not admit any liability. The defendants also continue to deny all allegations against them and to maintain that the suit has no merit. It is anticipated that the settlement will not have a material impact on the Company's business.

11. Subsequent Events

On July 6, 2016, the Company issued $460.0 million aggregate principal amount of 3.25% convertible senior notes due 2023 (the "convertible notes"). After deducting the underwriting discount and estimated offering expenses of approximately $12.3 million, we estimate that the net proceeds from the convertible notes offering were approximately $447.7 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 will initially be $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.

On July 19, 2016, the Company entered into an amendment to its lease agreement with Irvine Eastgate Office II LLC for additional office space in San Diego, California. The amendment provides the Company with an additional 11,177 square feet of space. The lease term is anticipated to end in September 2019. The rent for the first year will be approximately $254,832 and will gradually increase every twelve months throughout the lease term for the additional space. The Company will be responsible for a portion of the insurance, certain service charges and taxes for the building based on the floor area rented by it. The landlord provided the Company with an allowance of approximately $22,354 for improvements to the office space. Pursuant to the terms of the amendment, the Company provided the landlord with an additional letter of credit for $26,679.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2015 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 29, 2016. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Item 1.A. "Risk Factors" of our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases with high unmet medical need utilizing our proprietary bile acid chemistry. Our marketed product and clinical product candidates have the potential to treat orphan and more prevalent liver diseases for which, currently, there are limited therapeutic solutions.

Our lead product, obeticholic acid, or OCA, is a bile acid analog, a chemical substance that has a structure based on a naturally occurring human bile acid that selectively binds to and activates the farnesoid X receptor, or FXR. We believe OCA has broad liver-protective properties and may effectively counter a variety of chronic insults to the liver that cause fibrosis, or scarring, which can eventually lead to cirrhosis, liver transplant and death.

OCA was approved in the United States in May 2016 for use in patients with primary biliary cholangitis, or PBC, under the brand name Ocaliva®. We commenced sales and marketing of Ocaliva in the United States shortly after receiving such marketing approval, and Ocaliva is now available to patients primarily through our specialty pharmacy distributors. In June 2015, we received notice of the acceptance of the Marketing Authorization Application, or MAA, for review by the European Medicines Agency, or EMA, for use of Ocaliva in PBC. If we are successful in the EMA review process, we anticipate receiving conditional marketing approval in late 2016.

OCA is also being developed to treat a variety of other non-viral progressive liver diseases such as nonalcoholic steatohepatitis, or NASH, primary sclerosing cholangitis, or PSC, and biliary atresia. We are currently evaluating our future development strategy for OCA in other indications, for our product candidate INT-767 and for our pre-clinical

candidates.

OCA has been tested in five placebo-controlled clinical trials, including a Phase 3 clinical trial in patients with PBC and two Phase 2 clinical trials in patients with NASH or a precursor disease to NASH known as nonalcoholic fatty liver disease, or NAFLD. OCA met the primary efficacy endpoint in each of these trials with statistical significance. In addition, in October 2015, we announced results from a Phase 2 dose ranging trial of OCA in 200 patients with NASH in Japan conducted by our collaborator, Sumitomo Dainippon Pharma Co., Ltd., or Sumitomo Dainippon. The results of this trial were mixed and are described in more detail in the "Business" section of our Annual Report on Form 10-K for the period ended December 31, 2015. Sumitomo Dainippon has informed us that it is exploring the initiation of its registrational trials for OCA in NASH patients intended to support the registration of this indication in Japan. OCA has received orphan drug designation in the United States and the European Union for the treatment of PBC and PSC and breakthrough therapy designation from the U.S. Food and Drug Administration, or FDA, for the treatment of NASH patients with liver fibrosis.

OCA achieved the primary endpoint in a Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, which was sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health. The FLINT trial was completed in late July 2014. We have an ongoing Phase 3 clinical trial in non-cirrhotic NASH patients with liver fibrosis, known as the REGENERATE trial. We expect to complete enrollment of the 1,400 patients needed for the pre-planned interim histology analysis to be conducted after 72 weeks of treatment in the first half of 2017, which would potentially lead to results from the interim analysis to be available in 2019. We also have an ongoing Phase 2 clinical trial, known as the CONTROL trial, to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. We expect to complete enrollment of our CONTROL trial by the end of 2016. We continue to work towards expanding our overall NASH development program with additional trials and studies.

In addition to PBC and NASH, we continue to invest in research of OCA for additional patient populations with other liver diseases, including Phase 2 trials for PSC and pediatric patients with biliary atresia, respectively. We anticipate completing enrollment for our Phase 2 AESOP trial in PSC by the end of 2016. We have also initiated a Phase 1 trial in healthy volunteers for INT-767, a dual FXR and TGR5 agonist. We anticipate completing this Phase 1 trial for INT-767 by the end of 2016.

Our current patents for OCA are scheduled to expire at various times through 2033. Our current plan is to commercialize OCA ourselves in the United States and Europe for the treatment of PBC, NASH and other indications primarily by targeting physicians who specialize in the treatment of liver and intestinal diseases, including both hepatologists and gastroenterologists. We own worldwide rights to OCA except for Japan, China and Korea, where we have exclusively licensed OCA to Sumitomo Dainippon along with an option to exclusively license OCA in certain other Asian countries. We own or have rights to various trademarks, copyrights and trade names used in our business, including Ocaliva.

Our net loss for the three months ended June 30, 2016 and 2015 was approximately $77.3 million and $47.9 million, respectively. Our net loss for the six months ended June 30, 2016 and 2015 was $204.0 and $87.3 million, respectively. As of June 30, 2016, we had an accumulated deficit of approximately $899.6 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase as we:

- continue to commercialize Ocaliva for PBC in the United States;
- seek regulatory approval for and prepare to commercially launch Ocaliva for PBC in other jurisdictions;
- develop and seek regulatory approval for OCA in NASH and other indications;
- add infrastructure and personnel in the United States and internationally to support our product development and commercialization efforts; and
- operate as a public company.

We anticipate that we will need to raise additional capital to commercialize OCA on a worldwide basis and continue our research and development activities in relation to OCA and our other pipeline candidates. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise additional capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

On July 6, 2016, we completed an underwritten public offering of $460.0 million in aggregate principal amount of 3.25% convertible senior notes due 2023, or convertible notes. After deducting the underwriting discount and estimated offering expenses of approximately $12.3 million, we estimate that the net proceeds from the convertible notes offering were approximately $447.7 million. We used approximately $38.4 million of the net proceeds from the offering to fund the payment of the cost of the capped call transactions we entered into in connection with the issuance

of the convertible notes. We intend to use the remaining net proceeds from the offering together with our existing cash, cash equivalents and short-term investments, to fund the ongoing commercialization of Ocaliva in PBC in the United States; our preparation for and, subject to receipt of marketing approval, potential initiation of the commercial launch of Ocaliva in PBC in certain European countries as well as certain other target markets across the world; the continued clinical development of OCA in PBC, NASH and PSC; the advancement of our clinical program for INT-767; and continued advancement of other preclinical pipeline and research and development programs. We also intend to use the balance of the net proceeds from the offering, if any, for general corporate purposes, including general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property.

Our principal executive offices are in New York, New York. We also have administrative offices in San Diego, California and London, United Kingdom.

Financial Overview

Revenue

To date, we have not generated significant product sales. While we have commenced our commercial launch of Ocaliva for use in PBC in the United States in June 2016, we cannot predict the period, if any, in which material net cash inflows from sales of OCA or our other product candidates may commence. We do not expect to generate significant product sales in 2016.

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 until such time that all criteria are met.

We recognized net sales of Ocaliva for the second quarter 2016 of $75,000, pursuant to the product launch in June 2016. Cost of goods sold, or COGS during the second quarter of 2016 was only reflective of packaging and labeling costs incurred in the second quarter, which was de minimis. We expect COGS to remain negligible until previously expensed supplies of OCA are sold. We also recorded $2.7 million in deferred revenues on our balance sheet, which represents product shipped to distributors, but not sold through as of the end of June.

Substantially all of our revenue has been derived from our collaborative agreements for the development and commercialization of certain of our product candidates. We have entered into an exclusive licensing agreement with Sumitomo Dainippon for the development of OCA in Japan, China and Korea. Under the terms of the agreement, we have received up-front payments of $16.0 million, including $1.0 million upon the exercise by Sumitomo Dainippon of its option to add Korea to its licensed territories, and may be eligible to receive up to approximately $300 million in additional payments for development, regulatory and commercial sales milestones for OCA in the licensed territories. As of June 30, 2016, we have achieved $6.0 million of the development milestones.

For accounting purposes, the up-front payments are recorded as deferred revenue and amortized over time and milestone payments are recognized once earned. We recognized $5.9 million and $1.9 million in license revenue for the six months ended June 30, 2016 and 2015, respectively. For the six months ended June 30, 2016, $0.9 million resulted from the amortization of the up-front payments under the collaboration agreement and $5.0 million resulted from the milestone achieved in the period. For the six months ended June 30, 2015, $0.9 million resulted from the amortization of the up-front payments under the collaboration agreement and $1.0 million resulted from the milestone achieved in the period. We anticipate that we will recognize revenue of approximately $1.8 million per year through 2020, for the amortization of the relevant up-front collaboration payments from Sumitomo Dainippon. In the future, we expect to generate revenue primarily through product sales for Ocaliva.

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. We recognize research and development expenses as they are incurred. Beginning in the third quarter of 2016, as a result of the regulatory approval in the United States of Ocaliva for the treatment of PBC, we expect to capitalize inventory costs associated with the manufacturing of OCA for commercial use. Our research and development expenses consist primarily of direct costs, personnel costs and indirect costs such as the following:

Direct costs:

- fees paid to consultants and clinical research organizations, or CROs, including in connection with our preclinical activities and clinical trials, and other related fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- costs related to activities associated with acquiring and manufacturing OCA;
- costs associated with discovery and early stage research initiatives; and
- costs related to compliance with regulatory requirements.

Personnel costs:

- salaries and related benefit expenses for personnel in research and development functions; and
- costs related to stock compensation granted to personnel in research and development functions.

Indirect costs:

- rent and other facilities-related costs;
- product-related legal costs; and
- business travel and meeting costs.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of OCA for the treatment of PBC, NASH and PSC and other indications and to further advance the development of our other product candidates, subject to the availability of additional funding.

The table below summarizes our direct research and development expenses by program for the periods indicated. We do not allocate personnel costs and indirect costs related to our research and development function to specific product candidates. Those expenses are included in personnel costs and indirect research and development expense in the table below.