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.

	Six Months Ended June 30,	
	2016	2015
	(In thousands)	
Direct research and development expense by program:		
OCA	$35,159	$22,015
Research and discovery initiatives	2,524	4,704
INT-767	3,352	3,192
Total direct research and development expense	41,035	29,911
Personnel costs (1)	32,605	22,621
Indirect research and development expense	5,113	3,728
Total research and development expense	$78,753	$56,260

(1) Personnel costs, include stock-based compensation expense associated with stock options, restricted stock units, or RSUs, and restricted stock awards, or RSAs, granted to employees and non-employees of $7.5 million and $10.1 million for the six months ended June 30, 2016 and 2015, respectively.

The successful development of our clinical and preclinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our clinical or preclinical product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. We may also face delays in the regulatory review process, as we did with OCA in PBC where the target date for the FDA to take action under the Prescription Drug User Fee Act, or PDUFA, was extended from February 29, 2016 to May 29, 2016.

OCA

Prior to 2016, our research and development efforts were primarily focused on the development of OCA for PBC as well as the preparation and work required for our NDA and MAA filings and efforts related to working on the regulatory review process. Although we received accelerated approval by the FDA for Ocaliva for the treatment of PBC in May 2016, we are continuing our Phase 4 COBALT clinical outcomes confirmatory trial and are undergoing our regulatory review process with the EMA. We continue to invest with third-party manufacturers for supply chain and product development of OCA, prepare for PBC commercial launch in certain European countries and plan for the continuation of our clinical program in NASH, and work to secure additional manufacturers as part of our strategy to secure multiple approved suppliers of OCA in the future.

In addition, we are evaluating OCA in non-viral, progressive liver diseases other than PBC, particularly NASH, PSC and biliary atresia. We have the following trials underway as part of our OCA development program: our Phase 3 REGENERATE trial in non-cirrhotic NASH patients with liver fibrosis, the Phase 2 CONTROL trial to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients, the Phase 2 AESOP trial of OCA in patients with PSC and the Phase 2 CARE trial of OCA in patients with biliary atresia. We continue to work towards expanding our overall NASH development program with additional trials and studies. As a result, we expect that our expenditures in connection with our NASH, PSC and biliary atresia programs will increase significantly in future periods.

INT-767 and INT-777

We intend to continue to develop INT-767 and INT-777 (a selective TGR5 agonist). We initiated a Phase 1 clinical trial of INT-767 in healthy volunteers in November 2015. We also intend to conduct additional preclinical work on INT-777 to further characterize its therapeutic potential and to invest in product development in anticipation of further clinical trials.

Other than OCA, our product development programs are at early stages, and successful development of OCA and our future product candidates from these programs is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each future product candidate and are difficult to predict. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to our ability to maintain or enter into new strategic alliances with respect to each program or potential product candidate, the scientific and clinical success of each future product candidate, as well as ongoing assessments as to each future product candidate's commercial potential. We will need to raise additional capital and may seek additional strategic alliances in the future in order to advance our various programs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive and operational functions, including sales and marketing, finance, information technology, legal and human resources. Other significant general and administrative expenses include non-cash stock-based compensation expenses, expenses related to our OCA pre-commercialization activities, facilities costs, accounting and legal services, information technology and other expenses of operating as a public company.

Our general and administrative expenses have increased and will continue to increase due to the commercialization of Ocaliva for PBC in the United States, the potential commercialization of OCA in PBC internationally and development activities for OCA in indications other than PBC and for our other product candidates. We further plan on expanding our operations both in the United States and Europe, which will increase our general and administration expenses. We believe that these activities will result in increased costs related to the hiring of significant additional personnel, increased fees for outside consultants, lawyers and accountants, and the addition of facilities. We have also incurred and will continue to incur increased costs to comply with corporate governance, internal controls, compliance and similar requirements applicable to public companies with expanding operations and biopharmaceutical companies seeking to commercialize product candidates.

Other Income, Net

Other income, net consists of interest income earned on our cash, cash equivalents and investment securities, offset by amortization expense and investment management fees.

Results of Operations

Comparison of the Three Months Ended June 30, 2016 and the Three Months Ended June 30, 2015

The following table summarizes our results of operations for each of the three months ended June 30, 2016 and 2015, together with the changes in those items in dollars:

	Three Months Ended June 30,		Dollar Change
	2016	2015	
	(In thousands)		
Revenue			
Product revenue, net	$75	$-	$75
Licensing revenue	5,445	445	5,000
Total revenue	5,520	445	5,075
Operating expenses:			
Research and development	41,340	28,295	13,045
General and administrative	42,275	20,974	21,301
Loss from operations	(78,095)	(48,824)	(29,271)
Other income, net	796	930	(134)
Net loss	$(77,299)	$(47,894)	$(29,405)

Licensing and Product Revenue

Licensing revenue was $5.4 million and $0.4 million for the three months ended June 30, 2016 and 2015, respectively. For the three months ended June 30, 2016, $0.4 million resulted from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon and $5.0 million resulted from a milestone achieved in the period. For the three months ended June 30, 2015, $0.4 million resulted from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon.

Research and Development Expenses

Research and development expenses were $41.3 million and $28.3 million for the three months ended June 30, 2016 and 2015, respectively, representing a net increase of $13.0 million. This net increase in research and development

expense primarily reflects:

- net increase in OCA research and development activities of approximately $7.9 million; and
- additional personnel on our research and development team to manage the increased activities around our OCA program and other research and discovery initiatives, resulting in increased compensation costs of approximately $4.6 million. This reflects an increase of approximately $5.6 million in compensation, offset by a decrease in non-cash stock-based compensation of approximately $1.0 million.

General and Administrative Expenses

General and administrative expenses were $42.3 million and $21.0 million in the three months ended June 30, 2016 and 2015, respectively. The $21.3 million net increase primarily reflects:

- additional personnel-related costs of approximately $8.0 million to support our increased corporate initiatives. This reflects an increase of approximately $9.4 million in compensation, offset by a decrease in non-cash stock-based compensation of approximately $1.4 million;
- increased expenses of approximately $7.4 million in market research and other commercial pre-launch activities; and
- increased expenses of approximately $5.7 million for corporate initiatives to prepare for commercialization and to support future growth.

Other Income, Net

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which decreased compared to the prior year period as a result of increases in cash used in operations and lower investment balances.

Income Taxes

For the three months ended June 30, 2016 and 2015, no income tax expense or benefit was recognized. Our deferred tax assets are comprised primarily of net operating loss carryforwards. We maintain a full valuation allowance on our deferred tax assets since we have not yet achieved sustained profitable operations. As a result, we have not recorded any income tax benefit since our inception.

Comparison of the Six Months Ended June 30, 2016 and the Six Months Ended June 30, 2015

The following table summarizes our results of operations for each of the six months ended June 30, 2016 and 2015, together with the changes in those items in dollars:

	Six Months Ended June 30,		Dollar Change
	2016	2015	
	(In thousands)		
Revenue			
Product revenue, net	$75	$-	$75
Licensing revenue	5,891	1,891	4,000
Total revenue	5,966	1,891	4,075
Operating expenses:			
Research and development	78,753	56,260	22,493
General and administrative	132,707	34,112	98,595
Loss from operations	(205,494)	(88,481)	(117,013)
Other income, net	1,521	1,201	320
Net loss	$(203,973)	$(87,280)	$(116,693)

Licensing and Product Revenue

Licensing and product revenue was $5.9 million and $1.9 million 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 with Sumitomo Dainippon and $5.0 million resulted from a 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 with Sumitomo Dainippon and $1.0 million resulted from a milestone achieved in the period.

Research and Development Expenses

Research and development expenses were $78.8 million and $56.3 million for the six months ended June 30, 2016 and 2015, respectively, representing a net increase of $22.5 million. This net increase in research and development expense primarily reflects:

- increased expenses of approximately $13.1 million attributable to the expansion of OCA research and development; and
- additional personnel on our research and development team to manage the increased activities around our OCA program and other research and discover initiatives, resulting in an increase of approximately $10.0 million. This reflects an increase of approximately $12.6 million in compensation, offset by a decrease in non-cash stock-based compensation of approximately $2.6 million.

General and Administrative Expenses

General and administrative expenses were $132.7 million and $34.1 million in the six months ended June 30, 2016 and 2015, respectively. The $98.6 million net increase primarily reflects:

- one-time expense of approximately $45.0 million attributable to the settlement of the purported securities class action lawsuit, which reflects a settlement amount of $55.0 million deposited into escrow pending the final court order, of which $10.0 million was paid by our insurance carriers;
- increased personnel-related costs of approximately $19.8 million to support our increased corporate initiatives and commercialization activities. This reflects an increase of approximately $19.1 million in compensation, and an increase in non-cash stock-based compensation of approximately $0.7 million;
- increased expenses of approximately $12.1 million in market research and other pre-launch activities;
- increased expenses of approximately $12.0 million for corporate initiatives to prepare for commercialization and to support future growth; and
- increased operating costs such as facilities and technology-related expenses of approximately $9.2 million.

Other Income, Net

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which increased compared to the prior year period as a result of the increase in the investment balances from our April 2014, February 2015 and April 2015 equity financings, offset primarily by the increases in cash used in operations.

Income Taxes

For the six months ended June 30, 2016 and 2015, no income tax expense or benefit was recognized. Our deferred tax assets are comprised primarily of net operating loss carryforwards. We maintain a full valuation allowance on our deferred tax assets since we have not yet achieved sustained profitable operations. As a result, we have not recorded any income tax benefit since our inception.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2016, we had an accumulated deficit of $899.6 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain 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. Although OCA was approved in the United States in May 2016 for use in patients with PBC under the brand name Ocaliva and we commenced sales and marketing of Ocaliva shortly after receiving marketing approval in the United States, we do not expect to generate significant product sales in 2016.

We have funded our operations primarily through the sale of common stock, preferred stock, convertible notes and warrants and payments received under our collaboration agreements totaling $929.3 million (net of issuance costs of $33.7 million), including $29.7 million in net proceeds from our Series C financing in August 2012, $78.7 million in net proceeds from our initial public offering in October 2012, $61.2 million in net proceeds from our follow-on public offering in June 2013, $183.5 million in net proceeds from a follow-on public offering in April 2014, $191.6 million in net proceeds from a follow-on public offering in February 2015, $367.1 million in net proceeds from the follow-on offering in April 2015 and the receipt of $17.4 million in up-front payments under our licensing and collaboration agreements with Sumitomo Dainippon and Servier. As of June 30, 2016, we had cash, cash equivalents and investment securities of $439.5 million. 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. 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.

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods set forth below:

	Six Months Ended June 30,	
	2016	2015
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$(140,877)	$(63,595)
Investing activities	157,612	(431,813)
Financing activities	2,906	563,466
Effect of exchange rate changes	(682)	176
Net increase in cash and cash equivalents	$18,959	$68,234

Operating Activities. The increase in our net cash used in operating activities of approximately $77.3 million during the six months ended June 30, 2016 as compared to the same period last year was primarily a result of increased activities in our business requiring more capital. Net cash used in operating activities of $140.9 million during the six months ended June 30, 2016 was primarily a result of our $204.0 million net loss, offset by the add-back of non-cash expenses of $14.5 million for stock-based compensation, the amortization of investment premium of $2.7 million and a net increase in operating assets and liabilities of $42.6 million, including the $45 million net expense for settlement of the purported class action lawsuit. Net cash used in operating activities of $63.6 million during the six months ended June 30, 2015 was primarily a result of our $87.3 million net loss, offset by the add-back of non-cash expenses of $16.4 million for stock-based compensation, the amortization of investment premium of $2.6 million and net changes in operating assets and liabilities of $5.0 million.

Investing Activities. Net cash provided by investing activities for the six months ended June 30, 2016 was $157.6 million as compared to net cash used in investing activities for the six months ended June 30, 2015 of $431.8 million. This net increase in cash provided by investing activities of approximately $589.4 million is primarily attributed to an increase in sales of investment securities offset by a decrease in investment purchases and the $45.0 million for the settlement of the purported class action lawsuit. The cash payment for the net expense for the settlement of this lawsuit was made into an escrow account in the second quarter of 2016 pending final judgement.

Financing Activities. Net cash provided by financing activities for the six months ended June 30, 2016 were $2.9 million compared to $563.5 million for the comparable period in 2015. This decrease was primarily the result of funds received through the completion of the February 2015 and April 2015 offerings in the six months ended June 30, 2015 with no correlating financing in the six months ended June 30, 2016.

Convertible Senior Notes and Capped Call Transaction

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. 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. In connection with the offering, we entered into an indenture, as supplemented by the First Supplemental Indenture relating to the convertible notes, or collectively the Indenture, with U.S. Bank National Association, a national banking association, as trustee governing the convertible notes. The convertible notes bear interest at a rate of 3.25% per annum, 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. Holders may convert the convertible notes at their option at any time prior to the close of business on the business day immediately preceding January 1, 2023 only under the following circumstances: (1) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on September 30, 2016, if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (2) during the five business day period after any five consecutive trading day period, or the measurement period, in which the trading price (as defined in the Indenture) per $1,000 principal amount of convertible notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (3) if we call any or all of the convertible notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (4) upon the occurrence of specified corporate events. On or after January 1, 2023 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their convertible notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock (and cash in lieu of any fractional shares) or a combination of cash and shares of our common stock, at our election. The conversion rate will initially be 5.0358 shares of our common stock per $1,000 principal amount of convertible notes (equivalent to an initial conversion price of approximately $198.58 per share of common stock). The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will increase the conversion rate for a holder who elects to convert its convertible notes in connection with such a corporate event in certain circumstances.

We may not redeem the convertible notes prior to July 6, 2021. We may redeem for cash all or any portion of the convertible notes, at our option, on or after July 6, 2021, if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption 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. No sinking fund is provided for the convertible notes.

If we undergo a fundamental change, holders may require us to repurchase for cash all or any portion of their convertible notes at a fundamental change repurchase price equal to 100% of the principal amount of the convertible notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The convertible notes are our senior unsecured obligations and rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the convertible notes; equal in right of payment to our future unsecured indebtedness that is not so subordinated; effectively junior in right of payment to our future secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally subordinated to all existing and future indebtedness and other liabilities (including trade payables) incurred by our subsidiaries.

The Indenture contains customary events of default with respect to the convertible notes, including that upon certain events of default occurring and continuing, the trustee by notice to us, or the holders of at least 25% in principal amount of the outstanding convertible notes by notice to us, may (subject to the provisions of the Indenture) declare 100% of the principal of and accrued and unpaid interest, if any, on all the convertible notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization involving us or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the convertible notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

In connection with the pricing of the convertible notes, we entered into privately-negotiated capped call transactions with Royal Bank of Canada, or RBC, UBS AG, London Branch, or UBS, and Credit Suisse Capital LLC, or Credit Suisse. The aggregate cost of the capped call transactions entered into in connection with the pricing of the convertible notes was approximately $33.4 million. We and RBC, UBS and Credit Suisse entered into additional capped call transactions on July 1, 2016 in connection with the underwriters’ exercise of their over-allotment option in full at an aggregate cost of approximately $5.0 million. 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 our 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 our 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.

Future Funding Requirements

To date, we have not generated significant product sales and do not expect to generate significant product sales in 2016. While we 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 expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates.

We have incurred and expect to incur additional costs associated with our plans to further expand our operations in the United States, Europe and in certain other countries. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. As part of our longer term strategy, we also anticipate incurring significant expenses in connection with our planned increase in our product development, scientific, commercial and administrative personnel and expansion of our infrastructure and abroad. We anticipate that we will need substantial additional funding in connection with our continuing operations.

As of June 30, 2016, we had $439.5 million in cash, cash equivalents and investment securities. We currently project adjusted operating expenses in the lower end of the range of $360 million to $400 million in the fiscal year ending December 31, 2016, excluding the $45.0 million net expense for the settlement of the purported securities class action lawsuit, stock-based compensation and other non-cash items. These expenses are planned to support the continued clinical development program of OCA for PBC, NASH and PSC, increased OCA manufacturing activities, the continued development of INT-767 and other preclinical pipeline programs, as well as pre-commercialization and commercialization activities. We plan on making additional investments over 2016 should key regulatory milestones be achieved on a timely basis. Our adjusted operating expense estimate for 2016 is higher than our adjusted operating expenses for 2015 reflecting the increase in headcount that occurred in the latter part of 2015 and the anticipated increases in commercialization and research and development expenses. We anticipate that adjusted operating expenses will increase in the second half as compared to the first half of 2016.

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. 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.

Adjusted operating expense is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP. Other than the $45 million anticipated net expense for the class action lawsuit settlement, 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. See “Non-GAAP Financial Measures” for more information.

Due to the many variables inherent to the development and commercialization of novel therapies and our rapid growth and expansion, we currently cannot accurately and precisely predict the duration beyond mid-2018 over which we expect our cash and cash equivalents to be sufficient to fund our operating expenses and capital expenditure requirements. However, we currently believe that our cash and cash equivalents will be sufficient for us to:

- continue the initial commercialization of Ocaliva for PBC in the United States;
- prepare for and, if we obtain marketing approval on a timely basis, initiate the commercial launch of Ocaliva in PBC in certain European countries as well as certain other target markets across the world, but not commercially launch Ocaliva in PBC in other countries across the world;
- continue and expand our clinical development programs for OCA in PBC, NASH and PSC, such as continuing, but not completing, our planned Phase 3 clinical program for OCA in NASH, including the REGENERATE trial, our ongoing AESOP trial for OCA in PSC, and our ongoing COBALT confirmatory clinical outcomes trial of OCA in PBC; and
- advance the continued development of INT-767, including the completion of the ongoing Phase 1 clinical trial, and our preclinical compounds, but not completing the clinical or preclinical development needed to obtain regulatory approval, for and commercialize INT-767 or our preclinical compounds.

Accordingly, we will continue to require substantial additional capital in connection with our continuing operations, including continuing our commercialization plans and our research and development activities and building our global infrastructure to support these activities.

The amount and timing of our future requirements will depend on many factors including:

- the rate of progress and cost of our continued commercialization activities for Ocaliva in PBC in the United States;
- our ability to receive marketing approval of Ocaliva for PBC in Europe based on our regulatory submissions package and our work completed to date, including the willingness of the EMA to accept the POISE trial, which is our completed Phase 3 clinical trial for PBC;
- the degree of effort and time needed to prepare for and initiate the commercial launches of Ocaliva in PBC outside of the United States if we receive marketing authorization;
- the progress, costs, results of and timing of our clinical development programs for OCA in PBC, NASH and other indications, such as the sufficiency of the REGENERATE trial to be accepted as the sole pivotal trial for marketing approval or the acceptability of a surrogate endpoint for accelerated approval of OCA for the treatment of NASH and any modifications we may be required to make to the COBALT trial as part of our post-marketing requirements to the FDA or our regulatory interactions with the EMA;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the expansion of our research and development activities and the product candidates that we pursue, including INT-767 which is in a Phase 1 clinical trial, and our product candidates in preclinical development such as INT-777;

- the significant expansion of our operations, personnel and the size of our company and our need to continue to expand in the longer term;
- the costs associated with securing and establishing manufacturing capabilities and procuring the materials necessary for our product candidates;
- market acceptance of our product candidates, which may be affected by the reimbursement that our products receive from payors;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the effect of competing technological and market developments; and
- other cash needs that may arise as we continue to operate our business.

We have no committed external sources of funding. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Contractual Obligations and Commitments

Other than as described below, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 29, 2016.

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. In connection with the pricing of the convertible notes, we entered into privately-negotiated capped call transactions with RBC, UBS and Credit Suisse. See “—Liquidity and Capital Resources—Convertible Senior Notes and Capped Call Transaction” above.

On July 19, 2016, we entered into an amendment to our lease agreement with Irvine Eastgate Office II LLC for additional office space in San Diego, California. The amendment provides us 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. We will be responsible for a portion of the insurance, certain service charges and taxes for the building based on the floor area rented by us. The landlord provided us with an allowance of approximately $22,354 for improvements to the office space. Pursuant to the terms of the amendment, we provided the landlord with an additional letter of credit for $26,679.

Off-Balance Sheet Arrangements

As of June 30, 2016, we did not have any off-balance sheet arrangements as defined under the rules of the Securities and Exchange Commission.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates and there have been no material changes since our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 29, 2016.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our disclosure controls are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, are recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of June 30, 2016, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were adequate and effective.

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2016, in conjunction with Ocaliva receiving regulatory approval in the United States for PBC, we implemented processes and internal controls to record product revenues, deferred revenues, cost of sales and inventory. The implementation of these processes resulted in changes to our internal controls over financial reporting, which we believe were material. Further, we plan to continue to evaluate and enhance the design and documentation of our internal control over financial reporting process related to the recording of product revenues, cost of sales and inventory to maintain effective controls over our financial reporting.

There were no other changes in our internal control over financial reporting during the quarter ended June 30, 2016 identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time we are party to legal proceedings in the course of our business in addition to those described below. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

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 us and certain of our officers as defendants. These lawsuits were filed by stockholders who claim to be suing on behalf of anyone who purchased or otherwise acquired our securities between January 9, 2014 and January 10, 2014.

The lawsuits alleged that we made material misrepresentations and/or omissions of material fact in our 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 our 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, we 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 our 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.

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 our business.

Item 1A. Risk Factors.

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 1 of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We are dependent on the successful commercialization of Ocaliva® (obeticholic acid), which received accelerated approval in May 2016 from the U.S. Food and Drug Administration, or FDA, as a treatment for primary biliary cholangitis, or PBC. To the extent Ocaliva is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

Ocaliva (obeticholic acid, or OCA) is our only drug that has been approved for sale and it has only been approved in the United States for the treatment of PBC in combination with ursodiol in adults with an inadequate response to ursodiol or as monotherapy in adults unable to tolerate ursodiol.

Our ability to generate profits from operations and become profitable will depend on the success of commercial sales of Ocaliva. However, the successful commercialization of Ocaliva in PBC is subject to many risks. We are currently undertaking our first commercial launch with Ocaliva in PBC, and there is no guarantee that we will be able to do so successfully. There are numerous examples of unsuccessful product launches and failures to meet expectations of market potential, including by pharmaceutical companies with more experience and resources than us. We do not expect to generate significant product sales in 2016.

The commercial success of Ocaliva depends on the extent to which patients, physicians and payers accept and adopt Ocaliva as a treatment for PBC, and we do not know whether our or others' estimates in this regard will be accurate. While we have conducted pre-commercial activities, such as patient profiling, to better understand how physicians care for PBC patients, PBC is an orphan disease in which no new therapy has been approved in approximately 20 years. As such, there is significant uncertainty in the degree of market acceptance Ocaliva will have in PBC. For example, if the patient population suffering from PBC is smaller than we estimate, or even if the patient population matches our estimate but OCA is not widely accepted as a treatment for PBC, the commercial potential of Ocaliva will be limited. Physicians may not prescribe Ocaliva and patients may be unwilling to use Ocaliva if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, the use of Ocaliva in

a non-trial setting may result in the occurrence of unexpected or a greater incidence of side effects, adverse reactions or misuse that may negatively affect the commercial prospects of Ocaliva. Furthermore, any negative development in any other development program of OCA or our failure to satisfy the post-marketing regulatory commitments and requirements to which we are or may become subject, including potential modifications to and the completion of our Phase 4 COBALT trial, may adversely impact the commercial results and potential of Ocaliva.

As a result, we cannot foresee if Ocaliva will ever be accepted as a therapy in PBC that eventually results in revenues that can sustain operations. It may take the passage of a significant amount of time to generate sufficient revenues to sustain operations even if Ocaliva becomes accepted as a therapy in PBC. Furthermore, because Ocaliva is still undergoing regulatory review outside of the United States, we may not be able to commercialize Ocaliva in PBC outside of the United States, which may also limit our prospects. If the commercialization of Ocaliva for PBC is unsuccessful or perceived to be disappointing, the long-term prospects of Ocaliva and our company may be significantly harmed.

We have never been profitable. We expect to incur losses for the foreseeable future, and we may never achieve or sustain profitability.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses of $204.0 million during the six months ended June 30, 2016 and net losses of $226.4 million, $283.2 million and $67.8 million for the years ended December 31, 2015, 2014 and 2013, respectively. To date, we have financed our operations primarily through private placements of our convertible preferred stock, convertible notes and warrants to purchase common stock, public offerings of our common stock and payments received under our licensing and collaboration agreements with Sumitomo Dainippon Pharma Co., Ltd., or Sumitomo Dainippon, and Les Laboratoires Servier and Institut de Recherches Servier, which are collectively referred to as Servier. At June 30, 2016, we had $439.5 million in cash, cash equivalents and investment securities.

We have devoted substantially all of our resources to our development efforts relating to our product candidates, including conducting clinical trials of our product candidates, providing general and administrative support for these operations, protecting our intellectual property and engaging in activities to prepare for and commercially launch Ocaliva in PBC.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to 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 approvals for OCA in nonalcoholic steatohepatitis, or NASH, and other indications, and add infrastructure and personnel in the United States and internationally to support our product development and commercialization efforts and operations as a public company. We believe our prospects and ability to significantly grow revenues will be dependent on our ability to successfully develop and commercialize OCA for indications other than PBC such as NASH. As a result, we expect a significant amount of resources to continue to be devoted to our development programs for OCA.

As part of our product development activities, we anticipate that we will continue our Phase 4 COBALT trial of OCA in PBC including any modifications to the trial as may be agreed upon with regulatory authorities, continue our Phase 3 clinical program of OCA in NASH, including the Phase 3 REGENERATE trial in non-cirrhotic NASH patients with liver fibrosis, and continue our AESOP Phase 2 clinical trial of OCA for primary sclerosing cholangitis, or PSC. We also expect to continue the development of OCA in additional diseases, such as biliary atresia, a rare pediatric disease characterized by deficient bile duct development for which we initiated a Phase 2 trial in OCA called CARE. Our overall development program for OCA in NASH is expected to include a number of trials, such as a Phase 2 clinical trial, referred to as the CONTROL trial, to assess the lipid metabolic effects of OCA and the effects of concomitant statin administration in NASH patients. Furthermore, in November 2015, we initiated a Phase 1 clinical trial for INT-767, an earlier stage product candidate and we expect to incur further expenses as we continue to develop INT-767. Our expenses could increase if we are required by the FDA or the European Medicines Agency, or EMA, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates.

If OCA or any of our other product candidates fails in clinical trials or does not gain regulatory approval, or if our product candidates do not achieve market acceptance, we may never become profitable. Our net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We are currently advancing OCA through clinical development for multiple indications and other product candidates through various stages of clinical and preclinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive.

In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We have incurred and anticipate incurring significant expenses as we continue to commercialize Ocaliva in PBC, including significant expenses relating to our sales, marketing and distribution capabilities and increasing our drug manufacturing activities. As part of our longer-term strategy, we also anticipate incurring significant expenses in connection with our planned increase in our product development, scientific, commercial and administrative personnel and expansion of our facilities and infrastructure in the United States and abroad. We expect to incur additional costs associated with operating as a public company and further plan on expanding our operations in the United States, Europe and in certain other countries.

As of June 30, 2016, we had $439.5 million in cash, cash equivalents and investment securities. We currently project adjusted operating expenses in the lower end of the range of $360 million to $400 million in the fiscal year ending December 31, 2016, which excludes the $45.0 million net expense for the settlement of the purported securities class action lawsuit, stock-based compensation and other non-cash items. These expenses are planned to support the commercialization of Ocaliva in PBC, continued clinical development for OCA in PBC, NASH and PSC, increased OCA manufacturing activities and the continued development of INT-767 and other pipeline programs. We plan on making additional investments over 2016 should key regulatory milestones be achieved on a timely basis. Accordingly, we will continue to require substantial additional capital in connection with our continuing operations, including continuing our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete the research and development and commercialization of our products under development.

Adjusted operating expense is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP. Other than the $45 million net expense for the settlement of the purported class action lawsuit, 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. See “Non-GAAP Financial Measures” for more information.

Due to the many variables inherent to the development and commercialization of novel therapies, such as the risks described in this "Risk Factors" section of this quarterly report on Form 10-Q, and our rapid growth and expansion, we currently cannot accurately or precisely predict the duration beyond mid-2018 over which we expect our cash and cash equivalents to be sufficient to fund our operating expenses and capital expenditure requirements. However, we currently believe that our cash and cash equivalents will be sufficient for us to:

- continue the initial commercialization of Ocaliva for PBC in the United States;
- prepare for and, if we obtain marketing approval on a timely basis, initiate the commercial launch of Ocaliva in PBC in certain European countries as well as certain other target markets across the world, but not commercially launch Ocaliva in PBC in other countries across the world;
- continue and expand our clinical development programs for OCA in PBC, NASH and PSC, such as continuing, but not completing, our planned Phase 3 clinical program for OCA in NASH, including the REGENERATE trial, our ongoing AESOP trial for OCA in PSC, and our ongoing COBALT confirmatory clinical outcomes trial of OCA in PBC; and
- advance the continued development of INT-767, including the completion of the ongoing Phase 1 clinical trial, and our preclinical compounds, but not completing the clinical or preclinical development needed to obtain regulatory approval for and commercialize INT-767 or our preclinical compounds.

Accordingly, we will continue to require substantial additional capital in connection with our continuing operations, including continuing our commercialization plans and our research and development activities and building our global infrastructure to support these activities.

The amount and timing of our future funding requirements will depend on many factors, including:

- the rate of progress and cost of our continued commercialization activities for Ocaliva in PBC in the United States;
- our ability to receive marketing approval of Ocaliva for PBC in Europe based on our regulatory submissions package and our work completed to date, including the willingness of the EMA to accept the POISE trial, which is our completed Phase 3 clinical trial for PBC;
- the degree of effort and time needed to prepare for and initiate the commercial launches of Ocaliva in PBC outside of the United States if we receive marketing authorization;
- the progress, costs, results of and timing of our clinical development programs for OCA in PBC, NASH and other indications, such as the sufficiency of the REGENERATE trial to be accepted as the sole pivotal trial for marketing approval or the acceptability of a surrogate endpoint for accelerated approval of OCA for the treatment of NASH and any modifications we may be required to make to the COBALT trial as part of our post-marketing requirements to the FDA or our regulatory interactions with the EMA;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the expansion of our research and development activities and the product candidates that we pursue, including INT-767 which is in a Phase 1 clinical trial, and our product candidates in preclinical development such as INT-777;
- the significant expansion of our operations, personnel and the size of our company and our need to continue to expand in the longer term;

- the costs associated with securing and establishing manufacturing capabilities and procuring the materials necessary for our product candidates;
- market acceptance of our product candidates, which may be affected by the reimbursement that our products receive from payors;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the effect of competing