INTERCEPT PHARMACEUTICALS INC
Form 10-Q
May 10, 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 March 31, 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 (Address of Principal Executive Offices)	**10011 (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 April 15, 2016, there were 24,595,270 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:

- 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 obeticholic acid, or OCA, and any other product candidates we may develop, particularly the possibility that regulatory authorities may require clinical outcomes data (and not just results based on achievement of a surrogate endpoint) as a condition to any marketing approval for OCA, 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 our 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;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers;
- our collaborators’ election to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our need for and ability to obtain additional financing;
- our estimates regarding expenses, 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 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

	March 31, 2016 (Unaudited)	December 31, 2015 (Audited)
	(in thousands)	
Assets		
Current assets:		
Cash and cash equivalents	$49,205	$ 32,742
Investment securities, available-for-sale	507,655	595,313
Prepaid expenses and other current assets	18,086	13,638
Total current assets	574,947	641,693
Fixed assets, net	11,770	10,047
Security deposits	6,658	4,018
Total assets	$593,375	$ 655,758
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$42,470	$ 45,591
Litigation settlement	55,000	-
Short-term portion of deferred revenue	1,782	1,782
Total current liabilities	99,252	47,373
Long-term liabilities:		
Long-term portion of deferred revenue	5,790	6,236
Total liabilities	105,042	53,609
Stockholders' equity:		
Common stock 35,000,000 shares authorized; 24,594,025, and 24,391,430 shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively; par value $0.001 per share	25	24
Additional paid-in capital	1,311,739	1,300,008
Accumulated other comprehensive income (loss), net	(1,126)	(2,253)
Accumulated deficit	(822,305)	(695,630)
Total stockholders' equity	488,333	602,149
Total liabilities and stockholders' equity	$593,375	$ 655,758

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended March 31,	
	2016	2015
	(In thousands, except share and per share amounts)	
Licensing revenue	$ 445	$ 1,445
Costs and expenses:		
Research and development	37,413	27,966
General and administrative	90,432	13,138
Total costs and expenses	127,845	41,103
Other income (expense):		
Other income, net	726	272
	726	272
Net loss	$ (126,674)	$ (39,386)
Net loss per share:		
Basic and diluted	$ (5.17)	$ (1.78)
Weighted average shares outstanding:		
Basic and diluted	24,494,848	22,171,988

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Net loss	$(126,674)	$(39,386)
Other comprehensive loss:		
Unrealized gains (losses) on securities:		
Unrealized holding gains (losses) arising during the period	1,735	213
Reclassification for recognized gains (losses) on marketable investment securities during the period	(80)	2
Net unrealized gains (losses) on marketable investment securities	$1,654	$215
Foreign currency translation adjustments	(527)	(162)
Comprehensive loss	$(125,547)	$(39,333)

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Cash flows from operating activities:		
Net loss	$ (126,674)	$ (39,386)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	10,244	9,738
Depreciation	684	250
Amortization of investment premium	1,543	884
Changes in:		
Prepaid expenses, other current assets and security deposits	(7,088)	(3,546)
Accounts payable, accrued expenses and other current liabilities	(3,121)	2,912
Litigation settlement	55,000	-
Deferred revenue	(445)	(445)
Net cash used in operating activities	(69,857)	(29,594)
Cash flows from investing activities:		
Purchases of investment securities	(35,318)	(122,214)
Sales of investment securities	123,006	43,620
Purchases of equipment, improvements, and furniture and fixtures	(2,407)	(1,930)
Net cash provided by (used in) investing activities	85,281	(80,524)
Cash flows from financing activities:		
Proceeds from issuance of stock offerings, net of issuance costs	-	191,634
Proceeds from exercise of options	1,486	2,989
Net cash provided by financing activities	1,486	194,623
Effect of exchange rate changes	(447)	(162)
Net increase in cash and cash equivalents	16,463	84,343
Cash and cash equivalents – beginning of period	32,742	20,023
Cash and cash equivalents – end of period	$ 49,205	$ 104,366

See accompanying notes to the condensed consolidated financial statements.

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 (GAAP). The preparation of financial statements in conformity with 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.

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 up to $5.0 million for receiving marketing approval of OCA for PBC in the United States. As of March 31, 2016, the Company had achieved $1.0 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 March 31, 2016 and 2015, the Company recorded revenue of approximately $0.4 million and $1.4 million, respectively, in “Licensing Revenue” in its Condensed Consolidated Statement of Operations for the Company’s efforts under the agreement.

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 12 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 balance sheet in "Security Deposits."

4. Investments

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

	As of March 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	**Fair Value**
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$49,205	$ -	$ -	$49,205
Investment securities:				

Commercial paper	4,990	1	-	4,991
U.S. government and agency securities	72,395	13	(14)	72,394
Corporate debt securities	430,520	163	(411)	430,271
Total investments	507,905	177	(425)	507,656
Total cash, cash equivalents and investments	$557,110	$ 177	$ (425)	$556,861

	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 March 31, 2016, there were no marketable securities in a continuous unrealized loss position for more than twelve months.

5. Income Taxes

For the three months ended March 31, 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 March 31, 2016 and December 31, 2015, the Company had NOLs for U.S. federal income tax purposes of $470.4 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 $155.1 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	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(In thousands)			
March 31, 2016				
Assets:				
Money market funds	$35,295	$ 35,295	$ -	$ -
Available for sale securities:				-
Commercial paper	4,991	-	4,991	$ -
Corporate debt securities	72,394	-	72,394	-
U.S. government and agency securities	430,271	-	430,271	-
Total financial assets:	$542,951	$ 35,295	$ 507,656	$ -
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	
	March 31, 2016	December 31, 2015
	(In thousands)	
Due in one year or less	$350,027	$ 343,758
Due after 1 year through 2 years	157,629	251,555
Total investments in debt securities	$507,656	$ 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 March 31, 2016 and December 31, 2015, the Company had 35,000,000 authorized shares of common stock, $0.001 par value per share.

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 three months ended March 31, 2016:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2015	1,348,000	$ 108.49
Granted	371,300	$ 103.17
Exercised	(43,678)	$ 34.02
Expired	(2,781)	105.33
Forfeited	(10,003)	$ 173.59
Outstanding, March 31, 2016	1,662,838	$ 108.88
Exercisable, March 31, 2016	715,965	$ 64.38

The following table summarizes the aggregate RSU and RSA activity during the three months ended March 31, 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	194,455	$ 100.59	$ 24,981
Exercised	(30,551)	$ 121.99	$ (3,924)
Forfeited	(5,210)	$ 198.31	$ (669)
Non-vested shares outstanding, March 31, 2016	351,858	$ 142.63	$ 45,203

As of March 31, 2016, there was $45.3 million of unrecognized compensation expense related to unvested RSUs and RSAs, which is expected to be recognized over a weighted average of 3.19 years.

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

	Number of Shares	Price	Intrinsic Value (in thousands)
Employees and directors	347,922	$128.47	$ 44,698
Consultants	3,936	$128.47	506
Outstanding at March 31, 2016	351,858		$ 45,203

8. Net Loss Per Share

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

	Three Months Ended March 31,	
	2016	2015
	(In thousands, except share and per share amounts)	
Historical net loss per share		
Numerator:		
Net loss attributable to common stockholders	$ (126,674)	$ (39,386)

Denominator:		
Weighted average shares used in calculating net loss per share - basic and diluted	24,494,848	22,171,988
Net loss per share:		
Basic and diluted	$ (5.17)	$ (1.78)

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

	As of March 31,	
	2016	2015
	(In thousands)	
Options	1,663	1,290
Restricted stock units	352	119
Total	2,015	1,409

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 12 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. We are evaluating the impact of the adoption of the standard on our consolidated financial statements.

In March 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 has not yet assessed the impact of this update.

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 currently reviewing this standard to determine the implications.

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 Company reached an agreement with the lead plaintiff to seek Court approval of a proposed resolution. The proposed settlement contemplates payment of $55 million, of which $10 million will be funded by the Company's insurers. 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. The plaintiffs moved for preliminary approval of the proposed settlement on May 5, 2016, but the Court has not yet scheduled a hearing on that motion.

Following preliminary approval of the settlement, a notice will be sent to class members with information regarding the terms of the settlement, the plan for allocation and distribution of the settlement funds, claim procedures and the final settlement approval hearing. It is anticipated that the process will take several months.

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. Our product candidates have the potential to treat orphan and more prevalent liver diseases for which there currently are limited therapeutic solutions.

Our lead product candidate, 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, which we believe has broad liver-protective properties. OCA has been tested in five placebo-controlled clinical trials, including a Phase 3 clinical trial in patients with primary biliary cirrhosis, recently renamed primary biliary cholangitis, or PBC, and two Phase 2 clinical trials in patients with nonalcoholic fatty liver disease, or NAFLD, and nonalcoholic steatohepatitis, or NASH. 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.

In January 2015, OCA received breakthrough therapy designation from the U.S. Food and Drug Administration, or FDA, for the treatment of NASH patients with liver fibrosis. OCA has also been granted fast track designation by the FDA for the treatment of patients with PBC who have an inadequate response to or are intolerant of ursodiol. OCA has received orphan drug designation in the United States and the European Union for the treatment of PBC and primary sclerosing cholangitis, or PSC.

Our most advanced development program for OCA is for PBC as a second line treatment for patients who have an inadequate response to or who are unable to tolerate standard of care therapy and therefore need additional treatment. PBC is a chronic autoimmune liver disease that, if inadequately treated, may eventually lead to cirrhosis, liver failure and death. In March 2014, we completed a Phase 3 clinical trial, known as the POISE trial, in which OCA achieved the primary endpoint for the treatment of PBC. We intend to use these results, along with two previously completed randomized Phase 2 clinical trials of OCA for PBC, as the basis for seeking the first regulatory approvals to market OCA in the United States, Europe, Australia and Canada.

In June 2015, we completed our filings for marketing approval of OCA for PBC in the United States under the FDA's accelerated approval pathway. In August 2015, the FDA accepted for review our New Drug Application, or NDA, and granted Priority Review for OCA for the treatment of PBC. On April 7, 2016, the FDA's Gastrointestinal Drugs Advisory Committee voted unanimously (17 to 0) to recommend the accelerated approval of OCA for the treatment of patients with PBC. The target date for the FDA to take action under the Prescription Drug User Fee Act, or PDUFA, is May 29, 2016. The FDA is not bound by the advisory committee's guidance, but takes its advice into consideration when reviewing investigational medicines. If we receive marketing approval from the FDA, we plan to initiate the commercial launch of OCA for PBC in the United States in June 2016.

In June 2015, we also received notice of the acceptance of the Marketing Authorization Application, or MAA, by the European Medicines Agency, or EMA, for use of OCA for PBC. If we are successful in the EMA review process, we anticipate receiving marketing approval in late 2016, with planned commercial launches thereafter in certain European countries leading to anticipated revenues in 2017. We also plan to apply for marketing approval of OCA for PBC in other markets across the world such as Australia and Canada.

The brand name Ocaliva™ has been provisionally approved by the FDA and EMA, but Ocaliva is an investigational medicine that has not been granted marketing authorization or approval from any regulatory authority. We own or have rights to various trademarks, copyrights and trade names used in our business, including Ocaliva.

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 and the results were subsequently published online in *The Lancet* in November 2014. We initiated our Phase 3 clinical trial in non-cirrhotic NASH patients with liver fibrosis, known as the REGENERATE trial, in September 2015. 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. In December 2015, we initiated a 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.

In addition to PBC and NASH, we plan to continue our research of OCA in patient populations suffering from other liver diseases, as we believe that FXR has broad therapeutic potential. In December 2014, we initiated an international Phase 2 clinical trial, known as the AESOP trial, in patients with PSC to evaluate the effects of 24 weeks of treatment with varying doses of OCA compared to placebo. We anticipate completing enrollment for our AESOP trial by the end of 2016. In October 2015, we initiated a Phase 2 clinical trial, known as the CARE trial, of OCA in pediatric patients with biliary atresia. This trial will evaluate the effects of 11 weeks of OCA treatment where patients with biliary atresia will be randomized to varying doses of OCA or a control group receiving only their current treatment. As part of our development program, in November 2015, we initiated a Phase 1 clinical trial of our second product candidate to enter clinical development, called INT-767, a dual FXR and TGR5 agonist, in healthy volunteers. We anticipate completing this Phase 1 trial for INT-767 by the end of 2016. We are currently evaluating our future development strategy for OCA in other indications, for INT-767 and for our pre-clinical candidates.

Our net loss for the three months ended March 31, 2016 and 2015 was approximately $126.7 million and $39.4 million, respectively. As of March 31, 2016, we had an accumulated deficit of approximately $822.3 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 substantially as we:

- complete the development of our lead product candidate, OCA, for the treatment of PBC, and continue the development of OCA for NASH, PSC and other patient populations;
- seek to obtain regulatory approvals for OCA for PBC, NASH, PSC and other potential patient populations;
- prepare for the potential commercialization of OCA for PBC, including enhancing our sales, marketing and distribution capabilities and increasing our drug manufacturing activities;
- continue development of our other product candidates, such as INT-767, and engage in other research and development activities;
- maintain, expand and protect our intellectual property portfolio;

increase our product development, scientific, commercial and administrative personnel and expand our facilities and operations in the United States and abroad; and

· operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which is subject to significant uncertainty. Accordingly, 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 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.

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 any revenue from the sale of products. 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 March 31, 2016, we have achieved $1.0 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 $0.4 million and $1.4 million in license revenue for the three months ended March 31, 2016 and 2015 respectively. All of the revenue recognized in the three months ended March 31, 2016 related to the amortization of the up-front payments under the collaboration agreement. For the three months ended March 31, 2015, $0.4 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 may generate revenue from a combination of license fees and other up-front payments, research and development payments, milestone payments, product sales and royalties in connection with our collaborations. We expect that any revenue we generate will fluctuate from quarter-to-quarter as a result of the timing of our achievement of preclinical, clinical, regulatory and commercialization milestones, if at all, the timing and amount of payments relating to such milestones and the extent to which any of our products are approved and successfully commercialized by us or our collaboration partners. If our collaboration partners fail to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

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. 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.

	Three Months Ended March 31,	
	2016	2015
	(In thousands)	
Direct research and development expense by program:		
OCA	$ 13,354	$ 8,958
Research and discovery initiatives	2,310	3,626
INT-767	1,438	1,789
Total direct research and development expense	17,102	14,373
Personnel costs (1)	17,769	12,386
Indirect research and development expense	2,542	1,207
Total research and development expense	$ 37,413	$ 27,966

(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 $4.5 million and $6.0 million for the three months ended March 31, 2016 and 2015 respectively. During the three months ended March 31, 2016, we added 16 research and development personnel in support of our activities.

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. Furthermore, while our PDUFA action date for OCA in PBC is May 29, 2016 and, if OCA is approved, we anticipate generating sales revenues in 2016, we cannot predict the period, if any, in which material net cash inflows from OCA or our other product candidates may commence. 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 PDUFA was extended from February 29, 2016 to May 29, 2016.

OCA

During 2015, the majority of our research and development resources were focused on completing our NDA and MAA filings for OCA for the treatment of PBC, which were completed during June 2015. In August 2015, the FDA accepted our NDA for filing and granted priority review of OCA for the treatment of PBC. The FDA set a target date of May 29, 2016 to take action under PDUFA, after giving effect to a 90 day extension. In addition to the review by the FDA, we are undergoing our regulatory review process with the EMA.

In relation to OCA, we have incurred and expect to continue to incur significant expenses in connection with these efforts, including:

- Continuing the long-term safety extension phase of our Phase 3 POISE trial of OCA for PBC potentially through 2019.
- Continuing our Phase 4 COBALT clinical outcomes confirmatory trial for OCA in PBC which we expect to complete on a postmarketing basis.
- Contracting with third-party manufacturers to increase OCA manufacturing activities, including investing in supply chain and product development, preparing for PBC commercial launch and planning for the continuation of our clinical program in NASH, and working to secure additional manufacturers as part of our strategy to secure multiple approved suppliers of OCA in the future. We are building commercial supplies, including supplies of the starting material for manufacturing OCA.

- Contracting with and planning to engage a number of consultants and other third party vendors in relation to our seeking of regulatory approval and implementing various electronic software and systems in relation to our regulatory activities.

In addition, we are evaluating OCA in non-viral, progressive liver diseases other than PBC, particularly NASH, PSC and biliary atresia. We initiated our Phase 3 REGENERATE trial in non-cirrhotic NASH patients with liver fibrosis in September 2015, the Phase 2 CONTROL trial to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients in December 2015, the Phase 2 AESOP trial of OCA in patients with PSC in December 2014, and the Phase 2 CARE trial of OCA in patients with biliary atresia in October 2015. 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 potential commercialization of our 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. During the quarter ended March 31, 2016, we added 9 corporate and 4 commercial personnel in support of our activities.

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 March 31, 2016 and the Three Months Ended March 31, 2015

The following table summarizes our results of operations for each of the three months ended March 31, 2016 and 2015, together with the changes in those items in dollars:

	Three Months Ended March 31,		Dollar Change
	2016	2015	
	(In thousands)		
Licensing revenue	$445	$1,445	$ (1,000)
Operating expenses:			
Research and development	37,413	27,966	9,447
General and administrative	90,432	13,137	77,295
Loss from operations	(127,400)	(39,658)	(87,742)
Other income, net	725	272	453
Net loss	$(126,675)	$(39,386)	$ (87,289)

Licensing Revenue

Licensing revenue was $0.4 million and $1.4 million for each of the three months ended March 31, 2016 and 2015, respectively. For the three months ended March 31, 2016, $0.4 million resulted from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon. For the three months ended March 31, 2015, $0.4 million resulted from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon and $1.0 million resulted from the milestone achieved in the period.

Research and Development Expenses

Research and development expenses were $37.4 million and $28.0 million for the three months ended March 31, 2016 and 2015, respectively, representing a net increase of $9.4 million. This net increase in research and development expense primarily reflects:

- additional personnel on our development team to manage the increased activities around our OCA development program, resulting in increased compensation costs of approximately $5.4 million;
- increased OCA manufacturing activities of approximately $2.5 million to support our commercial scale manufacturing and investment in clinical operations;
- increased indirect expenses of approximately $1.3 million.

General and Administrative Expenses

General and administrative expenses were $90.4 million and $13.1 million in the three months ended March 31, 2016 and 2015, respectively. The $77.3 million net increase primarily reflects:

- a one-time net expense of $45.0 million arising from the settlement of the purported securities class action lawsuit, which reflects a settlement amount of $55.0 million of which $10.0 million is planned to be paid by our insurance carriers;
- additional personnel-related costs of approximately $17.9 million to support our increased corporate initiatives;
- increased expenses of approximately $5.9 million related to pre-commercialization activities, which include marketing and public relations;
- increased legal fees related to the defense of the purported securities class action litigation of approximately $4.5 million; and
- increased operating costs such as facilities and technology-related expenses of approximately $3.7 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 three months ended March 31, 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 March 31, 2016, we had an accumulated deficit of $822.3 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.

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 $623.2 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 March 31, 2016, we had cash, cash equivalents and investment securities of $556.9 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in cash and money market bank accounts and investments, all of which have maturities of less than two years.

Cash Flows

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

	Three Months Ended March 31,	
	2016	2015
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (69,857)	$ (29,594)
Investing activities	85,281	(80,524)
Financing activities	1,486	194,623
Effect of exchange rate changes	(447)	(162)
Net (decrease) increase in cash and cash equivalents	$ 16,463	$ 84,343

Operating Activities. The increase in our net cash used in operating activities of approximately $40.3 million during the three months ended March 31, 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 $69.9 million during the three months ended March 31, 2016 was primarily a result of our $126.7 million net loss, offset by the add-back of non-cash expenses of $10.2 million for stock-based compensation, the amortization of investment premium of $1.5 million and net changes in operating assets and liabilities of $10.2 million, including the $45 million net expense for the settlement of the purported class action lawsuit. The cash payment for the net expense for the settlement of this lawsuit is anticipated to be made in the second quarter of 2016. Net cash used in operating activities of $29.6 million during the three months ended March 31, 2015 was primarily a result of our $39.4 million net loss, offset by the add-back of non-cash expenses of $9.7 million for stock-based compensation, the amortization of investment premium of $0.8 million and net changes in operating assets and liabilities of $1.0 million.

Investing Activities. Net cash provided by investing activities for the three months ended March 31, 2016 was $85.3 million as compared to net cash used in investing activities for the three month ended March 31, 2015 of $80.5 million. This net increase in cash provided by investing activities of approximately $165.8 million is primarily attributed to an increase in sales of investment securities offset by a decrease in investment purchases.

Financing Activities. Net cash provided by financing activities for the three months ended March 31, 2016 were $1.5 million compared to $194.6 million for the comparable period in 2015. This decrease was primarily the result of funds received through the completion of the February 2015 offering in the first quarter of 2015 with no correlating financing in the first quarter of 2016.

Future Funding Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize OCA or any of our other product candidates. Even if we receive marketing approvals of OCA for PBC and commence our commercial launch, we do not expect to generate significant revenues in 2016. The FDA set a target date of May 29, 2016 to take action under PDUFA. We are also currently in the regulatory review process with the EMA. At the same time, 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 other countries such as Canada and Australia. 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 March 31, 2016, we had $556.9 million in cash, cash equivalents and investment securities. We currently project adjusted operating expenses in 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 believe that the build out of our U.S. commercial infrastructure is mostly complete with the hiring of a number of senior leaders in the U.S. commercial organization throughout 2015, along with the hiring of the U.S. territory business managers and other field personnel in October 2015. We also significantly expanded our commercial and other infrastructure internationally in 2015. Furthermore, we have devoted significant resources to building a global medical affairs team over the course of 2015 to support appropriate disease state, medical and scientific interactions with the healthcare and scientific community. 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.

Adjusted operating expense is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP. 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. 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 2016 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 and expand our clinical development programs of OCA for PBC, NASH and PSC, such as continuing, but not completing, our planned Phase 3 clinical program of OCA for NASH, including the REGENERATE trial, our ongoing AESOP trial of OCA for PSC, and our ongoing Phase 4 COBALT confirmatory clinical outcomes trial of OCA for PBC;

- advance the continued development of INT-767, including the completion of a recently initiated Phase 1 clinical trial, and our preclinical compounds, but not completing the clinical or preclinical development needed, as the case may be, for INT-767 or our preclinical compounds;

- increase OCA manufacturing activities, including investing in supply chain and product development, preparing for PBC commercial launch and planning for the continuation of our clinical program in NASH, but not manufacture the supply needed for any potential commercial launch of OCA for NASH;

- prepare for and, if we obtain marketing approval on a timely basis, initiate the commercial launch of OCA for PBC in both the United States and certain European countries, but not commercially launch OCA for PBC in other countries across the world; and

- expand, if necessary, our clinical, regulatory, medical affairs and commercial infrastructure through the time we initiate such planned commercial launch of OCA for PBC in both the United States and certain European countries, but not expand such infrastructure as may be required in the longer term.

Accordingly, we will continue to require substantial additional capital to continue our clinical development, commercialization and other activities. Because successful development and commercialization of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialization of our products under development.

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

- the willingness of the FDA and EMA to accept the POISE trial, which is our completed Phase 3 clinical trial for PBC, as well as our other clinical and preclinical studies and other work, as the basis for review and marketing approval of OCA for PBC;
- any limitations or restrictions on the indications or uses for OCA or any warnings that may be required to be included on the product label for OCA;
- the progress, costs, results of and timing of our Phase 4 COBALT confirmatory clinical outcomes trial of OCA for the treatment of PBC, the completion of which we expect will not be a condition to the receipt of marketing approval in the United States or the European Union, along with any post-approval commitments or requirements that we may be required to undertake as a condition to the approval of OCA;
- the progress, costs, results of and timing of the Phase 3 program and other supporting trials and studies necessary to support anticipated filings for marketing approval in NASH, including 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;
- the progress, costs, results of and timing of clinical development of OCA for other indications, including our Phase 2 AESOP trial of OCA for PSC and our Phase 2 CARE trial of OCA for biliary atresia;
- 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 outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of 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 ability of our product candidates to progress through preclinical and clinical development successfully and in a timely manner;
- the expansion of our research and development activities;
- the costs and timing of commercialization activities, including product sales, marketing and distribution, for any of our product candidates that receive marketing approval;
-

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;
- 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;
- our need and ability to hire and retain additional management, scientific and medical, commercial and other qualified personnel and the substantial cost of retaining such additional personnel;
- the effect of competing technological and market developments;
- our need to implement and maintain internal systems, software and infrastructure, including those to assist in our financial and reporting, clinical development and commercialization efforts and to support our personnel and operations as our business evolves; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

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.

In January 2016, Intercept Pharma Europe Ltd., or IPEL, our wholly owned subsidiary, entered into an underlease with Performing Right Society, Ltd. for additional office space in the King’s Cross area of London, United Kingdom. We are 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 £0.7 million (or approximately US$1.0 million), payable quarterly. IPEL is also required to pay 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 a rent deposit in an amount equal to 12 months’ rent, plus applicable VAT. The underlease is subject to an “upwards only” open market rent review of the current market rent with review to take place in June 2019.

In February 2016, we entered into a sublease with Restoration Hardware, Inc. for additional office space in New York City. The sublease provides us 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. We are also responsible for our proportionate share of increases in operating expenses beginning January 2017 as well as our 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, we delivered a letter of credit in the amount of approximately $0.3 million in favor of the sublandlord.

Off-Balance Sheet Arrangements

As of March 31, 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 March 31, 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

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), identified in connection with the evaluation of such internal control, that occurred during the three months ended March 31, 2016 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 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 we 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 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 proposed settlement contemplates payment of $55 million, of which $10 million will be funded by our insurers. 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. The plaintiffs moved for preliminary approval of the proposed settlement on May 5, 2016, but the Court has not yet scheduled a hearing on that motion.

Following preliminary approval of the settlement, a notice will be sent to class members with information regarding the terms of the settlement, the plan for allocation and distribution of the settlement funds, claim procedures and the final settlement approval hearing. It is anticipated that the process will take several months.

Item 1A. Risk Factors.

Other than as discussed below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2015 and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission. The risk factors described below update and supersede the corresponding risk factors contained in our Annual Report on Form 10-K, as updated in any subsequent periodic or current report. For a further discussion of our Risk Factors, refer to the “Risk Factors” discussion contained in such filings.

Risks Related to Regulatory Review and Approval of Our Product Candidates

We cannot be certain that obeticholic acid, or OCA, or any of our other product candidates will receive regulatory approval and the timeline of any such approval. Without regulatory approval we will not be able to market and commercialize our product candidates.

We are initially developing OCA for the treatment of patient populations with non-viral, progressive liver diseases, with a current principal focus on primary biliary cirrhosis, recently renamed primary biliary cholangitis, or PBC, nonalcoholic steatohepatitis, or NASH, and primary sclerosing cholangitis, or PSC, and our business currently depends entirely on the successful development and commercialization of OCA.

Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of OCA, particularly for the treatment of PBC and NASH, and our other product candidates.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, in the United States, the European Medicines Agency, or EMA, in Europe and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States or Europe until we receive approval of a New Drug Application, or NDA, from the FDA or a Marketing Authorization Application, or MAA, from the EMA, respectively. While we have completed the submissions of our NDA and MAA for OCA in PBC, we have not yet received marketing authorization from either the FDA or EMA for any of our product candidates.

NDAs and MAAs must include extensive preclinical and clinical data and supporting information to establish the product candidate’s safety and effectiveness for each desired indication. NDAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA or an MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. Even after the submission of an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We completed our filing of the NDA with the FDA and the MAA with the EMA in June 2015. In August 2015, the FDA accepted our NDA for filing and granted Priority Review for OCA for the treatment of PBC. On April 7, 2016, the FDA’s Gastrointestinal Drugs Advisory Committee voted unanimously (17 to 0) to recommend the accelerated approval of OCA for the treatment of patients with PBC. The target date for the FDA to take action under the Prescription Drug User Fee Act, or PDUFA, is May 29, 2016, after taking into a 90 day extension from February 29, 2016.

As part of the regulatory review process, the FDA and EMA will continue to review our submission package and conduct regulatory inspections of us and our vendors. We have provided responses as to many of the issues that have been identified in the regulatory review process and continue to respond with respect to others. We may be requested to provide further information, which may impact our regulatory review process. It remains possible that one or more of the issues identified to date, or other issues that may be identified by the FDA or EMA as the review process continues, may result in the FDA and/or the EMA not approving these marketing applications or delaying approval. Furthermore, even though the FDA generally follows the advice of its advisory committees, it is not bound by the recommendations of such committees and the design of our trial or data collected from such trial may not be adequate to demonstrate the safety and efficacy of OCA for the treatment of patients with PBC. As a result, we cannot be certain that our applications will be reviewed in a timely manner or approved by the FDA or the EMA.

Approvals may also be conditional upon the completion of one or more clinical trials. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Regulatory approval is also dependent on successfully passing regulatory inspection of our company, our clinical sites and key vendors and to ensure compliance with applicable good clinical, laboratory and manufacturing practices regulation. Critical findings could jeopardize or delay the approval of the NDA or MAA.

We will also be required to finalize the negotiations and discussions on our product labels for the respective jurisdictions in which we seek regulatory approval. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications or uses for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. For example, the FDA Advisory Committee discussed matters relating to the use of OCA in patients with moderately advanced and advanced hepatic impairment, the use of OCA as a monotherapy in PBC patients who are intolerant to ursodiol, the use of OCA in patients with different stages of PBC progression, and possible rules for stopping OCA treatment after a certain period if OCA does not produce a reduction in ALP. Also, regulatory approval for any of our product candidates may be withdrawn. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country.

We have completed a randomized, placebo-controlled Phase 3 trial of OCA in PBC patients, which we refer to as the POISE trial, and two randomized, placebo-controlled Phase 2 trials of OCA in PBC patients, one with OCA in combination with ursodiol and one with OCA as monotherapy. Following discussions with the FDA and EMA, we are also conducting our COBALT clinical outcomes confirmatory trial of OCA in PBC, which must be completed on a post-approval basis. Furthermore, we will need to complete a number of clinical trials and other studies for the continued development of OCA in indications other than PBC. For example, we initiated our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis in September 2015 and initiated our Phase 2 CONTROL trial to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients in December 2015. We also intend to complete our planning for a Phase 2 program in NASH patients with cirrhosis in 2016. In each of these cases, our ability to obtain the approvals necessary to commercialize our product candidates will depend on our ability to conduct and complete these additional trials as well as assemble various other data to complete our regulatory filings for OCA in the relevant indication or patient population.

There can be no assurance that we will be able to receive marketing approval for OCA in PBC or that we will be able to complete our regulatory filings for any other indication on a timely basis or at all. We cannot predict whether our trials and studies as to NASH or any other indication or patient population will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or require us to conduct additional studies or trials. For example, while OCA received breakthrough therapy designation from the FDA in January 2015 for the treatment of NASH patients with liver fibrosis, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulators will ultimately agree to a surrogate endpoint for accelerated approval of OCA for the treatment of NASH. While the interim histological endpoint is similar to that in the Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health, our Phase 3 REGENERATE trial has different trial designs. For example, the REGNERATE trial will include the following interim co-primary endpoints which are intended to serve as the basis for seeking marketing approvals in the United States, Europe and other countries: (i) the proportion of OCA-treated patients relative to placebo achieving at least one stage of liver fibrosis improvement with no worsening NASH and (ii) the proportion of OCA-treated patients relative to placebo achieving NASH resolution with no worsening of liver fibrosis. The REGENERATE trial will also remain blinded after the interim analysis and continue to follow patients until the occurrence of a pre-specified number of adverse liver-related clinical events, including progression to cirrhosis, to confirm clinical benefit on a post-marketing basis.

Furthermore, the Phase 2 dose ranging trial of OCA in 200 adult NASH patients in Japan conducted by our collaborator, Sumitomo Dainippon, did not meet its primary endpoint with statistical significance. In this trial, there was a dose dependent, although not statistically significant, increase in the percentage of OCA treated patients compared to placebo who achieved the primary endpoint (p=0.053). In addition, no difference was seen in fibrosis improvement in the OCA groups compared to placebo. The baseline characteristics between the patients in the Japanese Phase 2 trial conducted by Sumitomo Dainippon were distinct in a number of ways from those of the Western patients included in the Phase 2b FLINT trial conducted by NIDDK. For example, differences were observed among the patient population at baseline in relation to gender mix and metabolic factors like weight, diabetes status, dyslipidemia and hypertension. While our REGENERATE trial was designed based on the results of the FLINT trial and is anticipated to enroll a predominantly Western NASH patient population, the results of the FLINT trial may not

be replicated in our REGENERATE trial. Although Sumitomo Dainippon has informed us that it is exploring the initiation of a Phase 3 clinical trial for OCA in NASH patients intended to support the registration of this indication in Japan, the results may not be an improvement as compared to those from the Phase 2 trial on Japanese NASH patients.

If we are unable to obtain approval from the FDA, the EMA or other regulatory agencies for OCA and our other product candidates, or if, subsequent to approval, we are unable to successfully commercialize OCA or our other product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

We are developing product candidates for the treatment of rare diseases or diseases for which there are no or limited therapies and for some of which there is little clinical experience, and our development approach involves new endpoints and methodologies. As a result, there is increased risk that we will not be able to gain agreement with regulatory authorities regarding an acceptable development plan, the outcome of our clinical trials will not be favorable or that, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval.

Currently, there are no approved therapies for NASH or PSC. As a result, the design and conduct of clinical trials for these diseases and other indications we may pursue will be subject to increased risk.

The FDA generally requires two pivotal clinical trials to approve an NDA. Furthermore, for full approval of an NDA, the FDA requires a demonstration of efficacy based on a clinical benefit endpoint. Under Subpart H regulations, the FDA can grant accelerated approval based on a surrogate reasonably likely to predict clinical benefit. The POISE primary endpoint is a surrogate endpoint that we believe is reasonably likely to predict clinical benefit, therefore meeting the FDA's Subpart H requirements for consideration under its accelerated approval regulation. In August 2015, the FDA accepted our NDA for filing and granted Priority Review for OCA for the treatment of PBC. A target date of May 29, 2016 has been set to take action under PDUFA, after giving effect to a 90 day extension. It is unlikely we will receive definitive written guidance from the FDA prior to formal review of our NDA as to the acceptability of the POISE trial surrogate endpoint to support an approval of OCA for the treatment of PBC. Although the results from our POISE trial are highly significant and supported by two controlled Phase 2 trials, our POISE trial and our regulatory submissions package may nonetheless not be sufficient to support approval in the United States. In addition, it is possible that the FDA may not complete its review of our NDA by the specified PDUFA action date, may seek to delay our PDUFA date through a major amendment as it did in December 2015 for our NDA for OCA in PBC or may provide a complete response letter denying our application for marketing authorization. We anticipate that similar risks will apply to other indications for which we intend to seek marketing approval for our product candidates under accelerated approval regulations. For example, we will face these risks for OCA for the treatment of NASH because of our plan to seek accelerated approval based on the REGENERATE trial which incorporates interim co-primary surrogate endpoints.

In order to support the clinical utility of the surrogate endpoint for OCA as a treatment for PBC, we have sponsored an independent study pooling and analyzing long-term PBC patient data from a number of leading PBC academic centers, which we refer to as the Global PBC Study Group. Furthermore, an academic consortium in the United Kingdom has published the results of another large observational study in PBC patients in the United Kingdom. Also, even though the FDA's Gastrointestinal Drugs Advisory Committee voted unanimously to recommend the accelerated approval of OCA for the treatment of PBC based on its effect on ALP, the FDA is not bound by the recommendations of such committees and the design of our trial, including the surrogate endpoint, or data collected from such trial may not be adequate to demonstrate the safety and efficacy of OCA for the treatment of patients with PBC. As such, although we believe the results of both studies are supportive of the clinical utility of our surrogate endpoint for the use of OCA in PBC, the supporting data may still not be accepted by the FDA in its consideration of the adequacy of our surrogate endpoint under an NDA for OCA for the treatment of PBC. In addition to the risk around the acceptability of the surrogate biochemical endpoint to support accelerated approval, there are quality assurance risks around the data supporting assessment of the biochemical endpoint. It is possible that key parameters such as the validation of the assay and consistency across laboratories will not be acceptable to FDA and could delay or jeopardize approval of the NDA.

The FDA has also informed us that, even if it provides us an accelerated approval for OCA, we will be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of OCA in PBC by demonstrating the correlation of biochemical therapeutic response in patients taking OCA with a significant reduction in adverse clinical outcomes over time. Following discussions with the FDA, we initiated our COBALT clinical outcomes confirmatory trial in December 2014. There can be no assurance that our COBALT trial will confirm that the surrogate endpoints used for accelerated approval will eventually show an adequate correlation with clinical outcomes. If the COBALT trial fails to show such adequate correlation, we may not be able to maintain our previously granted marketing approval for OCA in PBC. Furthermore, the FDA Advisory Committee discussed the adequacy of the enrollment criteria and design of the COBALT trial, potentially broadening the inclusion of patients across the spectrum of stages of PBC. It is possible that further changes may be required to the protocol of the COBALT trial based on subsequent discussions with the FDA and EMA.

Likewise, while we completed our filing of the MAA with the EMA in June 2015, we will not receive definitive feedback from the EMA prior to formal review of our MAA as to the acceptability of the POISE trial endpoint to support a marketing authorization of OCA for the treatment of PBC. It is also possible that any marketing authorization we receive from the EMA for OCA for the treatment of PBC could be conditional on post-approval studies and not considered a full approval. Our ability to obtain and maintain conditional marketing authorization in the European Union will be limited to specific circumstances and subject to several conditions and obligations, if obtained at all, including the completion of a clinical outcomes trial to confirm the clinical benefit of OCA in PBC. Conditional marketing authorizations based on incomplete clinical data may be granted for a limited number of listed medicinal products for human use, including products designated as orphan medicinal products under European Union law, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, including with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data, may be specified in the conditional marketing authorization. Conditional marketing authorizations are valid for one year, and may be renewed annually, if

the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions.

Our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis, which was initiated in September 2015, incorporates interim co-primary surrogate endpoints that may serve as the basis for a supplemental NDA filing for accelerated approval in the United States and approval in Europe. Accelerated approval in the United States and conditional approval in the European Union for OCA in NASH are subject to similar risks as discussed above in relation to OCA for PBC. The primary endpoint in the Phase 2b FLINT trial of OCA in NASH patients was based on liver biopsy and was defined as an improvement of two or more points in the NAFLD activity score (a system of scoring the histopathological features in the liver), or NAS, with no worsening of liver fibrosis and the co-primary endpoints for our REGENERATE trial are: (i) the proportion of OCA-treated patients relative to placebo achieving at least one stage of liver fibrosis improvement with no worsening NASH and (ii) the proportion of OCA-treated patients relative to placebo achieving NASH resolution with no worsening of liver fibrosis. Currently, other biopharmaceutical companies are enrolling or have initiated trials in certain subpopulations of NASH patients based on different endpoints from those in the FLINT and REGENERATE trials. Although the FDA acknowledged at recent workshops the possibility of granting accelerated approval for NASH therapies using surrogate endpoints, with potential examples including histological improvement, using the NAS or another scoring system, histological resolution of NASH, or improvements in fibrosis in pre-cirrhotic patients with NASH, the FDA did not provide any formal regulatory guidance on approvable endpoints and may not accept a surrogate endpoint for OCA for the treatment of NASH.

The FDA generally requires two pivotal clinical trials to approve an NDA. Therefore, even if we achieve favorable results in a single Phase 3 clinical trial, the FDA may not accept this one trial as an adequate basis for approval and require that we conduct and complete a second Phase 3 clinical trial before considering an NDA for any of the indications for which we may seek marketing approval for our product candidates. Our NDA for OCA for the treatment of PBC patients who have an inadequate response to or are intolerant of ursodiol will be based on the results of three clinical trials — the POISE trial and two Phase 2 trials. It is possible that our final NDA submission for regulatory approval will not be accepted by the FDA for review or, even if it is accepted for review, that there may be delays in the FDA's review process and that the FDA may determine that our NDA does not merit the approval of OCA for the treatment of PBC, in particular because we have only conducted a single Phase 3 clinical trial of OCA for the treatment of PBC, in which case the FDA may require that we conduct and/or complete additional clinical trials and preclinical studies before it will reconsider our application for approval. A similar risk applies if we seek marketing approval of OCA for non-cirrhotic NASH patients with liver fibrosis based on the interim results of our REGENERATE trial. Our regulatory pathway for OCA for the treatment of NASH will depend upon our discussions with the FDA and EMA. As a result, we may face difficulty in designing an acceptable registration strategy around REGENERATE or any other trials in different subpopulations of NASH patients. In addition, since the design of the REGENERATE trial deviates from that of the FLINT trial, there is an increased risk that the results of the REGENERATE trial would differ from the FLINT results.

The EMA and regulatory authorities in other countries in which we may seek approval for, and market, OCA or our other product candidates may require additional preclinical studies and/or clinical trials prior to granting approval. It may be expensive and time consuming to conduct and complete additional preclinical studies and clinical trials that the FDA, EMA and other regulatory authorities may require us to perform. As such, any requirement by the FDA, EMA or other regulatory authorities that we conduct additional preclinical studies or clinical trials could materially and adversely affect our business, financial condition and results of operations. Furthermore, even if we receive regulatory approval of OCA for the treatment of any of our targeted indications, the labeling for our product candidates in the United States, Europe or other countries in which we seek approval may include limitations that could impact the commercial success of our product candidates.

Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for OCA and our other product candidates.

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We initiated our COBALT clinical outcomes confirmatory trial of OCA in PBC in December 2014, our Phase 2 AESOP trial of OCA in PSC in December 2014, our REGENERATE trial in September 2015, our Phase 2 CARE trial of OCA in biliary atresia in October 2015 and our Phase 2 CONTROL trial to assess the lipid metabolic effects of OCA and the effects of concomitant statin administration in NASH patients in December 2015. The results from these trials may not be available when we expect or we may be required to conduct additional clinical trials or preclinical studies not currently planned to receive approval for OCA as a treatment for the related indication, in which case we would require additional funding. In addition, our clinical programs are subject to a number of variables and contingencies, such as the results of other trials or regulatory interactions that may result in a change in timing. As such, we do not know whether any future

trials or studies of our other product candidates, including our COBALT trial, will begin on time or will be completed on schedule, if at all.

The commencement, enrollment and completion of clinical trials can be delayed or suspended for a variety of reasons, including:

- inability to obtain sufficient funds required for a clinical trial or lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials, which may occur at various times, including subsequent to the initiation of the clinical trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our product candidates;
- the delay in receiving results from or the failure to achieve the necessary results in other clinical trials;

- inability to obtain approval from institutional review boards, or IRBs, to conduct a clinical trial at their respective sites;

- severe or unexpected drug-related adverse effects experienced by patients or any determination that a clinical trial presents unacceptable health risks;

- a breach of the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates, including Sumitomo Dainippon and Servier or investigators leading clinical trials on our product candidates;

- inability to timely manufacture sufficient quantities of the product candidate required for a clinical trial;

- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our trial, the risks of procedures that may be required as part of the trial, such as a liver biopsy, and competition from other clinical trial programs for the same indications as our product candidates; and

- inability to retain enrolled patients after a clinical trial is underway.

For example, in the past, we experienced delays in our Phase 2 clinical trial of OCA given as a monotherapy to patients with PBC because we were unable to find and enroll a sufficient number of trial patients who met the specific enrollment criteria in accordance with our anticipated trial schedule.

Changes in regulatory requirements and guidance may also occur and we or any of our collaborators may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us or any of our collaborators to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

In addition, if we or any of our collaborators are required to conduct additional clinical trials or other preclinical studies of our product candidates beyond those contemplated, our ability to obtain regulatory approval of these product candidates and generate revenue from their sales would be similarly harmed.

Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate we, Sumitomo Dainippon, Servier or our potential future collaborators advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional

clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials and at other stages of clinical development, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If OCA or our other product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them, the prospects for approval of OCA would be materially and adversely affected and our business would be harmed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes or differences in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term stockholder value will be limited.

We believe that the results of our POISE trial and our long-term safety extension trials in PBC patients, which include patients who currently have been on OCA therapy for more than four years, demonstrate that OCA produces a durable therapeutic response. We completed our filings for marketing approval of OCA in PBC in the United States and the European Union in June 2015. In August 2015, the FDA accepted our NDA for filing and granted Priority Review for OCA for the treatment of PBC. On April 7, 2016, the FDA’s Gastrointestinal Drugs Advisory Committee voted unanimously (17 to 0) to recommend the accelerated approval of OCA for the treatment of PBC. The target date for the FDA to take action under PDUFA is May 29, 2016, after taking into account a 90 day extension from February 29, 2016. We cannot assure you that our POISE trial results, despite the positive FDA Advisory Committee vote, will result in our receiving marketing approval for OCA in PBC, or that our ongoing COBALT clinical outcomes confirmatory trial of OCA in PBC will demonstrate a correlation of biochemical therapeutic response in patients taking OCA with a significant reduction in adverse clinical events over time. In addition, it is possible that the FDA may not complete its review of our NDA by the specified PDUFA action date, may seek to delay our PDUFA date through a major amendment or may provide a complete response letter denying our application for marketing authorization.

In December 2014, we received comprehensive datasets from the FLINT trial, which met its primary endpoint with statistical significance. In October 2015, we announced that the Phase 2 dose ranging trial of OCA in the Sumitomo Dainippon Phase 2 trial did not meet its primary endpoint with statistical significance. In this trial, there was a dose dependent, although not statistically significant, increase in the percentage of OCA treated patients compared to placebo who achieved the primary endpoint (p=0.053). In addition, no difference was seen in fibrosis improvement in the OCA groups compared to placebo. The Phase 2 trial in NASH conducted in Japan by our collaborator Sumitomo Dainippon involved different doses of OCA being administered to the trial subjects than those utilized in FLINT. Furthermore, the baseline characteristics between the patients in the Japanese Phase 2 trial conducted by Sumitomo Dainippon were distinct in a number of ways from those of the Western patients included in FLINT. While our REGENERATE trial was designed based on the results of the FLINT trial and is anticipated to enroll a predominantly Western NASH patient population, the results of the FLINT trial may not be replicated in our REGENERATE trial. In addition, since the design of the REGENERATE trial deviates from that of the FLINT trial, there is an increased risk that the results of the REGENERATE trial would differ from the FLINT results. Even though OCA has been granted breakthrough therapy designation by the FDA, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulators will agree to a surrogate endpoint for accelerated approval of OCA for the treatment of NASH. As a result, it may take longer than anticipated to initiate and complete the Phase 3 REGENERATE trial or our Phase 3 program in NASH for other patient subpopulations.

Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require our product candidates to be taken off the market, require them to include safety warnings or otherwise limit their sales.

A substance that binds to a receptor of a cell and triggers a response by that cell is called an agonist. OCA has been shown to be a potent agonist of the farnesoid X receptor, or FXR. With the exception of the endogenous human bile acid chenodeoxycholic acid, or CDCA, and cholic acid, there are no approved FXR agonists and the adverse effects from long-term exposure to this drug class are unknown. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed.

The most common side effects observed in clinical trials of OCA in PBC were pruritus, or itching, fatigue, headaches, nausea, constipation and diarrhea. In our Phase 2 PBC clinical trial of OCA in combination with ursodiol, approximately 8% of the patients enrolled in the 10 mg and 25 mg dose groups withdrew from the trial due to severe pruritus. At the 50 mg dose, approximately 25% of the patients withdrew from the trial due to severe pruritus. In our POISE trial, pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment and was observed in 38% of patients on placebo, 68% of patients in the 10 mg OCA group and 56% of patients in the OCA titration group (5 mg to 10 mg). Eight patients discontinued due to pruritus, of whom none were in the placebo group, seven (10%) patients were in the 10 mg OCA group and one (1%) patient was in the OCA titration group (in a patient who had titrated up to 10 mg). Pruritus also has been observed in other clinical trials of OCA. Decreases in HDL cholesterol and small and transient increases in LDL cholesterol were also observed during treatment in the POISE trial.

Based on information in the manuscript for the FLINT trial published in November 2014, pruritus occurred more frequently in the OCA treatment group than in the placebo treatment group (23% vs. 6%, $p < 0.001$) and at a higher grade (predominately moderate pruritus), but resulted in only one patient discontinuation in the OCA treatment group. In the FLINT trial, OCA treatment was associated with changes in serum lipid levels, including increases in total cholesterol and LDL cholesterol and a decrease in HDL cholesterol, that were observed within 12 weeks of initiating treatment, peaked and then decreased in magnitude while on treatment, and reversed further during the 24-week post-treatment period. As previously disclosed, these changes in cholesterol levels, along with achieving the pre-defined efficacy criteria, played a role in the decision of the FLINT data and safety monitoring board to terminate the treatment phase of FLINT, and the publication of the FLINT results has noted the need for further study of these changes. In December 2015, we initiated CONTROL, a Phase 2 trial characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. There were two patient deaths in the FLINT trial that were previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013, and neither death was considered related to OCA treatment.

Additional or unforeseen side effects from these or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. If new side effects are found during the development of OCA for any indication, if known side effects are shown to be more severe than previously observed or if OCA is found to have other unexpected characteristics, we may need to abandon our development of OCA for PBC, NASH, PSC, biliary atresia and other potential indications.

The range and potential severity of possible side effects from systemic therapies is significant. The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings.

In addition, our drug candidates are being developed as potential treatments for severe, life threatening diseases and, as a result, our trials will necessarily be conducted in a patient population that will be more prone than the general population to exhibit certain disease states or adverse events. It is also possible that patients receiving treatment from OCA or our drug candidates for the labeled indication may suffer from other concomitant illnesses that may increase the likelihood of certain adverse events. It may be difficult to discern whether certain events or symptoms observed during our trials were due to our drug candidates or placebo, resulting in our company and our development programs being negatively affected even if such events or symptoms are ultimately determined to be unlikely related to our drug candidates. We further cannot assure you that additional or more severe adverse side effects with respect to OCA will not develop in future clinical trials, which could delay or preclude regulatory approval of OCA or limit its commercial use.

If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, Sumitomo Dainippon, Servier or our potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

Breakthrough therapy designation for OCA may not lead to faster development or regulatory processes nor does it increase the likelihood that OCA will receive marketing approval for NASH.

If a drug is intended for the treatment of a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development, the FDA may grant a breakthrough therapy designation. Breakthrough therapy designation is intended to facilitate the development, and expedite the review of such drugs, but the breakthrough therapy designation does not assure any such qualification or ultimate marketing approval by the FDA.

In January 2015, we received breakthrough therapy designation for OCA in the treatment of NASH patients with fibrosis. However, there is no guarantee that the receipt of breakthrough therapy designation will result in a faster development process, review or approval for OCA in fibrotic NASH patients or increase the likelihood that OCA will be granted marketing approval for fibrotic NASH patients. Likewise, any future breakthrough therapy designation for any other potential indication of OCA neither guarantees a faster development process, review or approval nor improves the likelihood of the grant of marketing approval by FDA for any such potential indication of OCA compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw any breakthrough therapy designation at any time. We may seek a breakthrough therapy designation for other of our product candidates, but the FDA may not grant this status to any of our proposed product candidates.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates, if approved, which would cause our revenues to suffer.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same product for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. In addition, it is possible that orphan drug designation in Europe will not be maintained following approval if the EMA determines that the product does not satisfy the requisite criteria including demonstration of significant clinical benefit. In November 2015, the European Commission set forth a consultation document and a notice detailing proposed amendments to the rules governing orphan medicinal products which may make it more difficult to demonstrate significant clinical benefit at the time of marketing authorization. The result of this process may impact our ability to maintain orphan drug designation in Europe.

The failure to maintain orphan status may impact our ability to receive a premium price for OCA or our other products and may subject us to mandatory price discounts in Europe. In addition, our ability to launch in Europe may be delayed and we may lose other benefits such as tax exemptions for sales. As such, the loss of orphan drug status may have a negative effect on our ability to successfully commercialize our products, earn revenues and achieve profitability.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Even after an orphan drug is approved, the FDA and EMA can subsequently approve the later product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance of our product candidates, if approved. If there is not sufficient reimbursement for our products or they are not covered at all, it is less likely that they will be widely used.

Market acceptance and sales of OCA or any other product candidates that we develop, if approved, will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for OCA or any other product candidates that we develop. Also, reimbursement policies could reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize OCA or any other product candidates that we develop.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. Any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the United States. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. The ACA requires discounts under the Medicare drug benefit program and increased the rebates paid by pharmaceutical companies on drugs covered by Medicaid. The ACA also imposes an annual fee, which increases annually, on sales by branded pharmaceutical manufacturers.

In addition, third-party payors attempt to contain health care costs by demanding price discounts or rebates and limiting both the types and variety of drugs that they will cover and the amounts that they will pay for drugs. As a result, they may not cover or provide adequate payment for our products. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products or any other future products to such payors' satisfaction. Such studies might require us to commit a significant amount of management's time and our financial and other resources. Our products might not ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Reimbursement in the European Union and many other territories must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. The timing to complete the negotiation process in each country is highly uncertain, and in some countries we expect that it may exceed 12 months. Even after a price is negotiated, countries frequently request or require adjustments to the price and other concessions over time. Reimbursement agencies in Europe are often more conservative than those in the United States and the reimbursement process is often slower since reimbursement decisions are made on a country-by-country basis.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of OCA and any other products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, commonly referred to as "fraud and abuse" laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions such as Europe have similar laws and are enacting more stringent regulations. These laws include false claims and anti-kickback statutes. If we market our products and our products are paid for by governmental programs, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service covered by Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

If the FDA and EMA and other regulatory agencies do not approve the manufacturing facilities of our future contract manufacturers for commercial production on a timely basis or at all, we may not be able to commercialize any of our product candidates or commercialization of our product candidates could be delayed.

We do not intend to manufacture the pharmaceutical products that we plan to sell. We currently have agreements with a contract manufacturer for the production of the active pharmaceutical ingredients and the formulation of sufficient quantities of drug product for the COBALT clinical outcomes confirmatory trial of OCA in PBC and the long-term safety extension phase of the POISE trial for OCA in PBC, our Phase 3 NASH program for OCA, including the REGENERATE trial, and the certain other trials and preclinical studies that we plan to conduct prior to and after seeking regulatory approval. If our contract manufacturer should cease to provide services to us for any reason, we likely would experience delays in advancing our clinical trials while we identify and qualify one or more replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us.

We do not have agreements for commercial supplies of OCA or any of our other product candidates. We currently obtain these supplies and services from our third-party contract manufacturers on a purchase order basis. We are currently seeking to qualify one or more back-up API manufacturers. While we have procured sufficient supplies for the commercial launch of OCA, we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to continue commercial sales of OCA on a long-term basis.

Additionally, the facilities used by any contract manufacturer to manufacture OCA or any of our other product candidates must be the subject of a satisfactory inspection before the FDA or the regulators in other jurisdictions approve the product candidate manufactured at that facility. We are completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and current good manufacturing practice requirements of any governmental agency whose jurisdiction to which we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates, including:

- the possibility that we are unable to enter into a manufacturing agreement with a third party to manufacture our product candidates;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs, prevent us from commercializing our product candidates successfully or disrupt the supply of our products after commercial launch. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the government agencies that regulate our products.

Even if our product candidates receive regulatory approval, we will still be subject to strict regulatory requirements governing manufacturing and marketing of our products and, as a result, we could face future development and regulatory difficulties.

Our product candidates, if approved, will also be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and EMA requirements and requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMPs. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and EMA and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products, if any, for indications or uses for which they are not approved.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our collaborators to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;

- impose other administrative or judicial civil or criminal penalties;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us, Sumitomo Dainippon, Servier or our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold by us during the three months ended March 31, 2016 that were not registered under the Securities Act of 1933, as amended, or Securities Act. Also included is the consideration, if any, received by us for the securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

Between January 1 and March 31, 2016, we did not issue or sell any shares on an unregistered basis.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Quarterly Report on Form 10-Q.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INTERCEPT PHARMACEUTICALS, INC.

Date: May 10, 2016 By: /s/ Mark Pruzanski, M.D.
Mark Pruzanski
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2016 By: /s/ Barbara Duncan
Barbara Duncan
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit Index

Exhibit Number	Description of Exhibit
3.1	Restated Bylaws of the Registrant (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on February 17, 2016).
10.1	Letter Agreement by and between the Registrant and Barbara Duncan, dated February 12, 2016. +
10.2	Underlease between the Registrant, Intercept Pharma Europe, Ltd. and Performing Right Society, Ltd. dated, January 22, 2016 (filed as Exhibit 10.12 to the Company's Annual Report on Form 10-K filed on February 29, 2016).
10.3	Office Sublease between the Registrant and Restoration Hardware, Inc., dated February 23, 2016 (filed as Exhibit 10.13 to the Company's Annual Report on Form 10-K filed on February 29, 2016).
10.4	Non-Employee Director Compensation Policy (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 17, 2016). +
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at March 31, 2016 (unaudited) and December 31, 2015, (ii) Condensed Consolidated Statements of Operations for the three month periods ended March 31, 2016 and 2015 (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Loss for the three month periods ended March 31, 2016 and 2015, (iv) Condensed Consolidated Statements of Cash Flows for the three month periods ended March 31, 2016 and 2015 (unaudited) and (v) Notes to Condensed Consolidated Financial Statements (unaudited).

+ Management contract or compensatory arrangement.