INTERCEPT PHARMACEUTICALS INC
Form 10-Q
November 09, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

For the transition period from to

Commission file number: 001-35668

INTERCEPT PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**22-3868459**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
450 West 15th Street, Suite 505 New York, NY	**10011**
(Address of Principal Executive Offices)	**(Zip Code)**

(646) 747-1000

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer	x	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of October 31, 2015, there were 24,331,526 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;
- the success of competing drugs that are or become available;
- our collaborators’ election to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers;
- our need for and ability to obtain additional financing;
- our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof;
- our use of our cash and short term investments; and
- our ability to attract and retain key scientific or management personnel.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements

largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2015, particularly in Item 1.A. Risk Factors and in our subsequent periodic and current reports filed with the Securities and Exchange Commission, including those filed in this Quarterly Report on Form 10-Q. Those risk factors, together with any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

NON-GAAP FINANCIAL MEASURES

This Quarterly Report on Form 10-Q presents projected adjusted operating expense, which is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP, and should be considered in addition to, but not as a substitute for, operating expense that we prepare and announce in accordance with GAAP. We exclude certain items from adjusted operating expense, such as stock-based compensation and other non-cash items, that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. 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

	September 30, 2015 (Unaudited)	December 31, 2014 (Audited)
	(in thousands)	
Assets		
Current assets:		
Cash and cash equivalents	$72,354	$20,023
Investment securities, available-for-sale	623,354	219,701
Prepaid expenses and other current assets	6,830	6,104
Total current assets	702,538	245,828
Fixed assets, net	10,207	5,852
Security deposits	4,002	2,469
Total assets	$716,747	$254,149
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$30,401	$13,459
Short-term portion of deferred revenue	1,782	1,782
Total current liabilities	32,183	15,241
Long-term liabilities:		
Long-term portion of deferred revenue	6,681	8,017
Total liabilities	38,864	23,258
Stockholders' equity:		
Common stock. 35,000,000 shares authorized; 24,255,192 and 21,415,243 shares issued and outstanding as of September 30, 2015 and December 31, 2014, respectively; par value $0.001 per share	24	21
Additional paid-in capital	1,286,740	700,355
Accumulated other comprehensive loss, net	(1,504)	(284)
Accumulated deficit	(607,377)	(469,202)
Total stockholders' equity	677,883	230,890
Total liabilities and stockholders' equity	$716,747	$254,149

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
Licensing revenue	$445	$445	$2,336	$1,296
Costs and expenses:				
Research and development	27,487	27,381	83,747	56,593
General and administrative	24,742	9,136	58,854	22,742
Total costs and expenses	52,229	36,517	142,601	79,335
Other income (expense):				
Revaluation of warrants	-	-	-	(170,832)
Other income, net	889	228	2,090	469
	889	228	2,090	(170,363)
Net loss	$(50,896)	$(35,843)	$(138,175)	$(248,402)
Net loss per share:				
Basic and diluted	$(2.10)	$(1.69)	$(5.89)	$(12.07)
Weighted average shares outstanding:				
Basic and diluted	24,214,913	21,260,303	23,472,026	20,583,146

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
Net loss	$(50,896)	$(35,843)	$(138,175)	$(248,402)
Other comprehensive loss:				
Unrealized losses, net, on securities:				
Unrealized holding losses, net, arising during the period	(25)	(190)	(707)	(287)
Reclassification for recognized gains on marketable investment securities during the period	-	20	2	24
Net unrealized losses on marketable investment securities	$(25)	$(170)	$(705)	$(263)
Foreign currency translation adjustments	(690)	-	(514)	-
	$(715)	$(170)	$(1,220)	$(263)
Comprehensive loss	$(51,611)	$(36,013)	$(139,395)	$(248,665)

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
	(in thousands)	
Cash flows from operating activities:		
Net loss	$ (138,175)	$ (248,402)
Adjustments to reconcile net loss to net cash used in operating activities:		
Revaluation of warrants	-	170,832
Share-based compensation	22,038	16,464
Depreciation	1,059	210
Loss on the disposal of property and equipment	-	21
Amortization of investment premium	4,517	2,391
Changes in:		
Prepaid expenses, other current assets and security deposits	(2,259)	(4,269)
Accounts payable, accrued expenses and other current liabilities	16,942	7,455
Deferred revenue	(1,336)	(296)
Net cash used in operating activities	(97,216)	(55,595)
Cash flows from investing activities:		
Purchases of investment securities	(559,928)	(195,977)
Sales of investment securities	151,053	70,045
Purchases of equipment, leasehold improvements, and furniture and fixtures	(5,414)	(3,690)
Net cash used in investing activities	(414,289)	(129,622)
Cash flows from financing activities:		
Proceeds from issuance of stock offerings, net of issuance costs	558,756	183,475
Proceeds from exercise of options	5,595	6,438
Net cash provided by financing activities	564,351	189,913
Effect of exchange rate changes	(514)	-
Net increase in cash and cash equivalents	52,331	4,696
Cash and cash equivalents – beginning of period	20,023	13,363
Cash and cash equivalents – end of period	$ 72,354	$ 18,059

See accompanying notes to the condensed consolidated financial statements.

1. Nature of Business and Basis of Presentation

Intercept Pharmaceuticals, Inc. (“Intercept” or the “Company”), is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic underserved 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.

The Company has its administrative headquarters in New York, New York and offices in San Diego, California and London, United Kingdom. Intercept was incorporated in Delaware in September 2002.

Basis of Presentation

All financial information presented includes the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The unaudited financial statements of the Company included herein reflect all adjustments, consisting only of normal recurring adjustments, which in the opinion of management are necessary to fairly state the Company’s financial position, results of operations and cash flows for the periods presented. Interim results may not be indicative of the results that may be expected for the full year. Certain information and footnote disclosures normally included in the audited financial statements prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”) have been condensed or omitted pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, which are included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2014 for a broader discussion of the Company’s business and opportunities and risks inherent in such business.

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, 2014.

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 (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 for OCA for NASH in Japan, $10.0 million for receiving marketing approval for OCA for NASH in China, and up to $5.0 million for receiving marketing approval for OCA for PBC in the United States. As of September 30, 2015, 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 September 30, 2015 and 2014, the Company recorded revenue of approximately $445,000 and $445,000, respectively, and during the nine months ended September 30, 2015 and 2014, the Company recorded revenue of approximately $2.3 million and $1.3 million, respectively, in "Licensing Revenue" in its Condensed Consolidated Statement of Operations for the Company's efforts under the agreement. For the nine months ended September 30, 2015, $1.3 million resulted from the amortization of the up-front payments under the collaboration agreement and $1.0 million resulted from the development milestone achieved in the period. All of the revenue recognized in the nine months ended September 30, 2014 related to the amortization of the up-front payments under the collaboration agreement.

United Kingdom Lease

In February 2015, the Company entered into an underlease with Merck Sharp & Dohme Limited for the Company's new office in the King's Cross area of London, United Kingdom. The lease provides the Company with approximately 6,000 rentable square feet in London for office space. The lease term is anticipated to end in June 2019.

The annual rent is £470,608 payable quarterly. The Company is also required to pay value added tax (VAT) on the rent. The Company is responsible for a portion of the insurance, certain service charges and taxes for the building based on the floor area rented by the Company. As security for the underlease, the Company has provided the landlord with a rent deposit in the amount of £705,912 (or approximately $1.1 million), plus applicable VAT. The amount of the deposit may be reduced to £470,608 within 30 days after April 30, 2016 if there are no outstanding payments due and there are no material breaches of the underlease that have not been remedied in respect of which a drawdown notice has been served and has expired.

4. Investments

The following table summarizes the Company's cash, cash equivalents and investments as of September 30, 2015 and December 31, 2014:

	As of September 30, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Cash and cash equivalents:				
Cash and money market funds	$72,354	$ -	$ -	$72,354
Investment securities:				
Commercial paper	6,986	1	(1)	6,986
Corporate debt securities	550,483	67	(1,050)	549,500
U.S. government and agency securities	66,867	18	(17)	66,868
Total investments	624,336	86	(1,068)	623,354
Total cash, cash equivalents and investments	$696,690	$ 86	$ (1,068)	$695,708

	As of December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
Cash and cash equivalents:				
Cash and money market funds	$20,023	$ -	$ -	$20,023
Investment securities:				
Commercial paper	7,995	-	(1)	7,994
Corporate debt securities	203,988	19	(282)	203,725
U.S. government and agency securities	7,998	-	(16)	7,982
Total investments	219,981	19	(299)	219,701
Total cash, cash equivalents and investments	$240,004	$ 19	$ (299)	$239,724

As of September 30, 2015, there were no marketable securities in a continuous unrealized loss position for more than twelve months.

5. Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. The Company establishes a valuation allowance when it believes it is more likely than not that deferred tax assets will not be realized.

At September 30, 2015 and December 31, 2014, the Company had available net operating loss carryforwards to reduce future taxable income of approximately $289.0 million and $208.9 million, respectively, for tax reporting purposes. These carryforwards expire between 2024 and 2035. The ability of the Company to utilize its net operating losses in future years is subject to limitation in accordance with provisions of Section 382 of the Internal Revenue Code due to previous ownership changes; however, these changes have not resulted in material limitations to the Company’s ability to utilize the net operating losses. The Company’s deferred tax asset of approximately $160.3 million and $104.7 million at September 30, 2015 and December 31, 2014, respectively, resulted primarily from the tax effects of net operating losses, share-based compensation and deferred revenue. The Company does not have any deferred tax liabilities. Since the Company has not yet achieved sustained profitable operations, management believes its deferred tax assets do not satisfy the more-likely-than-not realization criteria and has provided an allowance for the full amount of the deferred tax asset. As a result, the Company has not recorded any income tax benefit since its inception.

6. Warrants to Purchase Common Stock

In conjunction with various financing transactions prior to its initial public offering, the Company issued warrants to purchase the Company's common stock. Certain of the warrants included a so-called "down round" provision that provides for a reduction in the warrant exercise price if there are subsequent issuances of additional shares of common stock for consideration per share less than the per share warrant exercise prices and the remaining warrants contain a provision that require the underlying shares to be registered upon an initial public offering (IPO). These warrants were deemed to be derivative instruments and as such, were recorded as a liability and were marked-to-market at each reporting period. The Company estimated the fair values of the warrants at each reporting period using a Black-Scholes option-pricing model. Management concluded, under the Company's facts and circumstances, that the estimated fair values of the warrants using the Black-Scholes option-pricing model approximates, in all material respects, estimated values determined using a binomial valuation model. The estimates in the Black-Scholes option-pricing model and the binomial valuation model were based, in part, on subjective assumptions, including but not limited to stock price volatility, the expected life of the warrants, the risk free interest rate and the fair value of the common stock underlying the warrants. Changes in the fair value of the common stock warrant liability from the prior period were recorded as a component of other income and expense.

On April 10, 2014, all the Company's remaining warrants to purchase a total of 865,381 shares of its common stock were exercised on a cashless basis into 834,758 shares of the Company's common stock and as such no further revaluations are required.

7. 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:

	Total	Fair Value Measurements Using Quoted Prices	Significant	Significant

		in Active Markets for Identical Assets or Liabilities (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
	(in thousands)			
September 30, 2015				
Assets:				
Money market funds	$32,828	$32,828	$ -	$ -
Available for sale securities:				
Commercial paper	6,986	-	6,986	-
Corporate debt securities	549,500	-	549,500	-
U.S. government and agency securities	66,868	-	66,868	-
Total financial assets	$656,182	$32,828	$623,354	$ -
December 31, 2014				
Assets:				
Money market funds	$21,284	$21,284	$ -	$ -
Available for sale securities:				-
Commercial paper	7,994	-	7,994	-
Corporate debt securities	203,725	-	203,725	-
U.S. government and agency securities	7,982	-	7,982	-
Total financial assets	$240,985	$21,284	$219,701	$ -

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

	Fair Value as of	
	September 30, 2015	December 31, 2014
	(in thousands)	
Due in one year or less	$349,437	$ 130,159
Due after 1 year through 2 years	273,917	89,542
Total investments in debt securities	$623,354	$ 219,701

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 September 30, 2015 and December 31, 2014, the Company had 35,000,000 authorized shares of common stock, $0.001 par value per share.

In October 2012, the Company completed the IPO of its common stock pursuant to a registration statement on Form S-1. In the IPO, the Company sold an aggregate of 5,750,000 shares of common stock under the registration statement at a public offering price of $15.00 per share. Net proceeds were approximately $78.7 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all outstanding shares of the Company’s preferred stock were converted into 7,403,817 shares of common stock.

In June 2013, the Company completed a public offering of 1,989,500 shares of its common stock pursuant to a registration statement on Form S-1. Net proceeds were approximately $61.2 million, after deducting underwriting discounts and commissions and offering expenses paid by the Company.

In April 2014, the Company completed a public offering of 1,000,000 shares of its common stock, of which 600,000 shares were sold by the Company and 400,000 shares were sold by certain selling stockholders pursuant to a registration statement on Form S-3. After underwriting discounts and commissions and offering expenses, the Company received net proceeds from the offering of approximately $183.5 million. The Company did not receive any proceeds from the sale of shares of common stock by the selling stockholders.

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.

8. 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 nine months ended September 30, 2015:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2014	1,436,055	$ 75.81
Granted	85,315	$ 221.10
Exercised	(258,844)	$ 21.49
Forfeited/Expired	(59,029)	$ 111.68
Outstanding, September 30, 2015	1,203,497	$ 96.04
Exercisable, September 30, 2015	641,241	$ 43.68

The following table summarizes the aggregate RSU and RSA activity during the nine months ended September 30, 2015:

	Number of Shares	Weighted Average Fair Value	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2014	119,348	$ 126.48	$ 19,795
Granted	74,041	$ 226.56	$ 12,280
Vested	(51,820)	$ 109.38	$ (8,595)
Forfeited	(7,933)	$ 211.98	$ (1,316)
Outstanding, September 30, 2015	133,636	$ 183.48	$ 22,165

As of September 30, 2015, there was $22.2 million of unrecognized compensation expense related to unvested RSUs and RSAs, which is expected to be recognized over a weighted average period of 3.27 years. The weighted average remaining contract life of the unvested shares as of September 30, 2015 is 3.27 years.

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

	Number	Intrinsic Value

	of Shares	(in thousands)
Employees and directors	127,333	$ 21,120
Consultants	6,303	1,045
Outstanding at September 30, 2015	133,636	$ 22,165

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9. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands, except share and per share amounts)			
Historical net loss per share				
Numerator:				
Net loss attributable to common stockholders	$(50,896)	$(35,843)	$(138,175)	$(248,402)
Denominator:				
Weighted average shares used in calculating net loss per share - basic and diluted	24,214,913	21,260,303	23,472,026	20,583,146
Net loss per share:				
Basic and diluted	$(2.10)	$(1.69)	$(5.89)	$(12.07)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
Options	1,203	1,343	1,203	1,343
Restricted stock units	25	71	25	71
Total	1,228	1,414	1,228	1,414

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 allege 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 claim 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. 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 intend to file a sur-reply. The parties are currently undergoing discovery in relation to this matter.

The lead plaintiff seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees.

The Company believes that it has valid defenses to the claims in the lawsuit and intends to deny liability and defend itself vigorously. There can be no assurance, however, that the Company will be successful. At this time, no assessment can be made as to the likely outcome of this action or whether the outcome will be material to the Company. Therefore, the Company has not accrued for any loss contingencies related to this lawsuit.

The Company may become subject to claims and assessments from time to time in the ordinary course of business. Such matters are subject to uncertainties and outcomes are not predictable with assurance. The Company accrues liabilities for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of September 30, 2015, the Company does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial condition, results of operations or cash flows.

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, 2014 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2015. 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 chronic underserved 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, 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 in which OCA met the primary efficacy endpoint with statistical significance, including a Phase 3 clinical trial in patients with primary biliary cirrhosis, or PBC, and two Phase 2 clinical trials in patients with nonalcoholic fatty liver disease, or NAFLD, and nonalcoholic steatohepatitis, or NASH. In addition, we recently 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 the current standard of care or as monotherapy for those 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 in PBC, as the basis for seeking the first regulatory approvals to market OCA in the United States, Europe, Canada and Australia. In June 2015, we completed our filings for marketing approval of OCA in PBC in the United States under the FDA's accelerated approval pathway and Europe in June 2015. In August 2015, the FDA accepted our NDA and granted Priority Review for OCA for the treatment of PBC and set a target date of February 29, 2016 to take action under the Prescription Drug User Fee Act, or PDUFA. We also plan to apply for marketing approval of OCA in PBC in other markets such as Canada and Australia. If we receive marketing approval from regulatory authorities, we plan to initiate the commercial launch of OCA in PBC in the United States, certain European countries and Canada in 2016.

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 July 2014. We initiated our Phase 3 clinical program in non-cirrhotic NASH patients with liver fibrosis, known as the REGENERATE trial, in September 2015. We are also initiating a Phase 2 dose ranging trial with the primary goal of evaluating the effects of OCA on LDL-C, as well as the effect of concomitant statin administration in NASH patients. We also recently announced the results from the Phase 2 dose ranging trial of OCA in 200 patients with NASH in Japan conducted by Sumitomo Dainippon, as described below under the caption "—Recent Developments—Sumitomo Dainippon Phase 2 Dose Ranging Trial of OCA in NASH."

Our net loss for the three months ended September 30, 2015 and 2014 was approximately $50.9 million and $35.8 million, respectively. Our net loss for the nine months ended September 30, 2015 and 2014 was $138.2 million and $248.4 million, respectively. As of September 30, 2015, we had an accumulated deficit of approximately $607.3 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 and, for the nine months ended September 30, 2014, from the mark-to-market of our previously outstanding liability-classified warrants.

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 in NASH and other patient populations;
- seek to obtain regulatory approvals for OCA for PBC, NASH and other potential patient populations;
- prepare for the potential commercialization of OCA in PBC, including establishing 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.

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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.

We have our headquarters in New York, New York and offices in San Diego, California and London, United Kingdom.

Recent Developments

Sumitomo Dainippon Phase 2 Dose Ranging Trial of OCA in NASH

On October 28, 2015, we announced the results of a 72-week Phase 2 dose ranging trial of OCA in 200 adult patients with NASH in Japan. The trial was conducted by our collaborator, Sumitomo Dainippon. In this trial, 202 Japanese biopsy-proven NASH patients (NAFLD Activity Score, or NAS, of 5-8) were randomized into one of four arms to receive either a 10mg, 20mg or 40mg dose of OCA, or placebo, and 200 of these patients – 50 per group – initiated treatment for a 72-week double-blind treatment phase, followed by a 24-week off treatment phase which is still ongoing. The primary endpoint was histologic improvement defined as at least a two point improvement in NAS with no worsening of fibrosis.

The primary efficacy analysis was conducted on an intention to treat, or ITT, basis, testing the dose dependent effects of once daily OCA (10mg, 20mg and 40mg) versus placebo on the primary endpoint. The ITT analysis included all randomized patients who received treatment (50 per group), and patients who discontinued or did not have a repeat biopsy were treated as non-responders. A pre-specified completer analysis was conducted on the patients who had biopsies at both baseline and 72 weeks (45, 44, 44 and 37 patients in the placebo, 10mg, 20mg and 40mg OCA groups, respectively).

The ITT results in the table below show a dose dependent increase in the percentage of OCA treated patients compared to placebo who achieved the primary endpoint (p=0.053, not significant). The 40mg OCA dose group

achieved statistical significance on the primary endpoint compared to placebo (p=0.0496). Dose-dependent trends not reaching statistical significance were also observed for several other pre-specified histologic endpoints, including the proportion of patients with steatosis and inflammation improvement, ballooning resolution and NASH resolution. No difference was seen in fibrosis improvement in the OCA groups compared to placebo.

ITT Results	**Placebo N=50**	**10mg N=50**	**20mg N=50**	**40mg N=50**	
NAS improvement ≥ 2 points with no worsening of fibrosis	10 (20%)	11 (22%) p=0.8070**	14 (28%) p=0.3378**	19 (38%) p=0.0496**	p=0.053*

* Primary efficacy analysis is a stratified Cochran-Armitage test with multiple contrast coefficients. Statistical significance is based on a p-value < 0.05.

** The secondary efficacy analysis is a CMH (Cochran-Mantel-Haenszel) test stratified by baseline fibrosis stage for pairwise comparison of each OCA group compared to the placebo group. The multiplicity was not adjusted.

In the completer analysis, similar dose dependent effects were observed, with 51% of patients in the 40mg dose group compared to 22% in the placebo group meeting the primary endpoint (p=0.0061).

With the exception of dose dependent pruritus, OCA appeared to be generally safe and well tolerated. The number of pruritus associated discontinuations were 0, 0, 2 and 5 patients in the placebo, 10mg, 20mg and 40mg OCA groups, respectively. Changes in lipid parameters, including LDL-C, HDL-C and triglycerides, appeared to be consistent with previously reported lipid changes in Western NASH patients. No other meaningful differences in the rate of adverse events between the OCA and placebo groups were noted.

Initiation of Phase 3 REGENERATE Trial for OCA in NASH Patients with Advanced Liver Fibrosis

In September 2015, we initiated the previously announced international Phase 3 trial of OCA in patients with non-cirrhotic NASH with advanced liver fibrosis, known as the REGENERATE trial. The REGENERATE trial was designed following discussions with the FDA and European Medicines Agency, or EMA. The study population is expected to primarily be comprised of Western NASH patients with stage 2 or stage 3 liver fibrosis. In addition, the trial will include an exploratory cohort of NASH patients with early stage 1 liver fibrosis and concomitant diabetes, obesity or elevated alanine aminotransferase, or ALT, who are at increased risk of progression to cirrhosis.

REGENERATE has been designed as a double-blind, placebo-controlled Phase 3 clinical trial and is expected to enroll approximately 2,000 NASH patients at up to 300 qualified centers worldwide and assess the potential benefits of OCA treatment on liver-related and other clinical outcomes. The trial will include a pre-planned interim histology analysis after 72 weeks of treatment in 1,400 patients, which if successful is intended to serve as the basis for seeking initial U.S. and international marketing approvals of OCA for the treatment of NASH patients with fibrosis. Two co-primary endpoints will be assessed in the interim analysis: (i) fibrosis improvement with no worsening of NASH and (ii) NASH resolution with no worsening of fibrosis.

Phase 2 Clinical Trial of OCA in Biliary Atresia

In October 2015, we initiated a Phase 2 clinical 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. The primary endpoint is to evaluate the pharmacokinetics and the safety and tolerability of OCA treatment. In addition, OCA's effect on hepatobiliary indices and biomarkers will be assessed. This trial is anticipated to enroll approximately 60 patients in the United States and Europe. All patients will be given the option to enroll in an open-label long-term safety and efficacy extension trial. In addition to studying the effects of OCA treatment in biliary atresia, this trial is a part of the approved Pediatric Investigation Plan in support of the MAA for OCA in PBC in the European Union.

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 September 30, 2015, 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 $2.3 million and $1.3 million in license revenue for the nine months ended September 30, 2015 and 2014, respectively. For the nine months ended September 30, 2015,

$1.3 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. All of the revenue recognized in the nine months ended September 30, 2014 related to the amortization of the up-front payments under the collaboration agreement. 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; and
- product-related legal 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
Direct research and development expense by program:				
OCA	$13,943	$19,611	$35,710	$34,535
Research and discovery initiatives	417	-	5,161	-
INT-767	836	425	4,028	1,293
Total direct research and development expense	15,196	20,035	44,899	35,828
Personnel costs (1)	10,460	6,091	33,051	18,114
Indirect research and development expense	1,831	1,255	5,797	2,651
Total research and development expense	$27,487	$27,381	$83,747	$56,593

(1) Personnel costs, which include stock-based compensation expense associated with stock options and restricted stock awards granted to employees and non-employees were $2.9 million and $2.9 million for the three months ended September 30, 2015 and 2014, respectively and $13.0 million and $10.3 million for the nine months ended

September 30, 2015 and 2014, respectively. For the nine months ended September 30, 2015, we had a net increase of 86 research and development personnel in support of our expansion in activities as compared to the number of research and development personnel in support of our expansion in activities as of December 31, 2014.

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 or the period, if any, in which material net cash inflows from these 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.

OCA

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 and granted priority review for OCA for the treatment of PBC, which set a target date of February 29, 2016 for the FDA to take action under PDUFA. In addition, we have incurred and expect to continue to incur significant expenses in connection with these efforts, including:

- Completing our POISE trial of OCA in patients with PBC in March 2014 and continuing the long-term safety extension phase of the trial potentially through 2019.
- Initiating our clinical outcomes confirmatory trial for OCA in PBC in December 2014 and continuing the trial on a post-marketing basis.
- Conducting numerous Phase 1 clinical trials during 2014 in support of the NDA and MAA filings for OCA in PBC.
- Contracting with third-party manufacturers to produce the quantities of OCA needed for regulatory approval as well as the necessary supplies for our other contemplated trials and working to secure second manufacturers as part of our strategy to secure more than one approved supplier 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 other chronic liver diseases, particularly NASH, PSC and biliary atresia. We initiated the REGENERATE trial in September 2015. We are also initiating a Phase 2 dose ranging trial with the primary goal of evaluating the effects of OCA on LDL-C, as well as the effect of concomitant statin administration in NASH patients. We initiated a Phase 2 clinical trial of OCA in PSC in December 2014 and a Phase 2 clinical trial of OCA in pediatric 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

We intend to continue to develop INT-767 (a dual FXR/TGR5 agonist) and INT-777 (a selective TGR5 agonist). Currently, we plan to initiate a Phase 1 trial of INT-767 in healthy volunteers around year end 2015 and will begin product development in anticipation of further clinical trials. We also intend to conduct additional preclinical work on INT-777 to further characterize its therapeutic potential.

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 as we operate as a public company and due to the potential commercialization of our product candidates. We further plan on expanding our operations both in the United States, Europe and other countries such as Canada and Australia, 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. For the nine months ended September 30, 2015, we had a net increase of 72 corporate and commercial personnel in support of our expansion in activities as compared to the number of corporate and commercial personnel in support of our expansion in activities as of December 31, 2014.

Other Income, Net

Other income, net consists of interest income earned on our cash, cash equivalents and investment securities, offset by management fees, as well as capital base, franchise and real estate taxes.

Revaluation of Warrants

In conjunction with various financing transactions prior to our initial public offering, we issued warrants to purchase shares of our common stock. As of June 30, 2014, all of the warrants have either been exercised or expired in accordance with their terms. Certain of the warrants that were outstanding during 2014 included a provision that provided for a reduction in the warrant exercise price upon subsequent issuances of additional shares of common stock for consideration per share less than the applicable per share warrant exercise price. The warrants containing this provision were deemed to be derivative instruments and as such, were recorded as a liability and marked-to-market at each reporting period. The fair value estimates of these warrants were determined using a Black-Scholes option-pricing model and were based, in part, on subjective assumptions. Non-cash changes in the fair value of the common stock warrant liability from the prior period were recorded as a component of other income and expense.

Results of Operations

Comparison of the Three Months Ended September 30, 2015 and the Three Months Ended September 30, 2014

The following table summarizes our results of operations for each of the three months ended September 30, 2015 and 2014, together with the changes in those items in dollars:

	Three Months Ended September 30,		Dollar Change
	2015	2014	
	(in thousands)		
Licensing revenue	$445	$445	$-
Operating expenses:			
Research and development	27,487	27,381	106
General and administrative	24,742	9,136	15,606

Loss from operations	(51,784)	(36,072)	15,713
Warrant revaluation income	-	-	-
Other income, net	889	228	(660)
Net loss	$(50,896)	$(35,843)	$15,052

Licensing Revenue

Licensing revenue was $445,000 for each of the three months ended September 30, 2015 and 2014 resulting from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon.

Research and Development Expenses

Research and development expenses were $27.5 million and $27.4 million for the three months ended September 30, 2015 and 2014, respectively, representing a net increase of $106,000. This net increase in research and development expense primarily reflects:

- increased expenses of $4.4 million related to personnel and activities to support our increased development initiatives;
- increased expenses of approximately $417,000 related to our research and discovery initiatives;
- increased costs of $411,000 associated with our INT-767 program;
- increased indirect costs of approximately $576,000; offset by
- decreased direct expenses of $5.7 million of which approximately $4.0 million related to product development and manufacturing, which occurred in the third quarter of 2014.

General and Administrative Expenses

General and administrative expenses were $24.7 million and $9.1 million in the three months ended September 30, 2015 and 2014, respectively. The $15.6 million net increase primarily reflects:

- increased expenses of approximately $7.3 million for personnel-related costs to support our increased corporate initiatives;
- increased expenses of approximately $5.1 million related to legal, finance and facilities costs to support our growing operations; and
- increased expenses of approximately $3.2 million related to commercialization expenses in preparation of the potential launch of OCA in 2016.

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.

Comparison of the Nine Months Ended September 30, 2015 and the Nine Months Ended September 30, 2014

The following table summarizes our results of operations for each of the nine months ended September 30, 2015 and 2014, together with the changes in those items in dollars:

	Nine Months Ended September 30,		Dollar Change
	2015	2014	
	(in thousands)		
Licensing revenue	$2,336	$1,296	$1,040
Operating expenses:			
Research and development	83,747	56,593	27,154
General and administrative	58,854	22,742	36,112
Loss from operations	(140,265)	(78,039)	62,226
Warrant revaluation (expense)	-	(170,832)	170,832

Other income, net	2,090	469	1,621
Net loss	$(138,175)	$(248,402)	$234,679

Licensing Revenue

Licensing revenue was $2.3 million and $1.3 million for the nine months ended September 30, 2015 and 2014, respectively. For the nine months ended September 30, 2015, $1.3 million resulted from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon and $1.0 million resulted from the development milestone achieved in the period. All of the revenue recognized in the nine months ended September 30, 2014 related to the amortization of the up-front payments under the collaboration agreement.

Research and Development Expenses

Research and development expenses were $83.7 million and $56.6 million for the nine months ended September 30, 2015 and 2014, respectively, representing a net increase of approximately $27.2 million. This increase in research and development expense primarily reflects:

- increased expenses of $14.9 million related to personnel and activities to support our increased development initiatives;
- increased expenses of approximately $5.2 million from research and discovery initiatives;
- increased indirect expenses of approximately $3.1 million; and
- increased expenses of $2.7 million associated with our INT-767 program.

General and Administrative Expenses

General and administrative expenses were $58.8 million and $22.7 million in the nine months ended September 30, 2015 and 2014, respectively. The $36.1 million net increase primarily reflects:

- increased expenses of approximately $18.0 million for personnel-related costs to support our increased corporate initiatives;
- increased expenses of approximately $10.0 million related to legal, finance and facilities costs to support our growing operations; and
- increased expenses of approximately $8.1 million which includes infrastructure activities of approximately $4.4 million (including systems and technology and travel) to support our development initiatives, as well as pre-commercialization activities of approximately $3.7 million, (including market research, launch preparation training and disease awareness costs).

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 by the increases in cash used in operations.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2015, we had an accumulated deficit of $607.3 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 September 30, 2015, we had cash, cash equivalents and investment securities of $695.7 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:

	Nine Months Ended September 30,	
	2015	2014
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$(97,215)	$(55,595)
Investing activities	(414,289)	(129,622)
Financing activities	564,350	189,913
Effect of exchange rate changes	(514)	-
Net increase in cash and cash equivalents	$52,331	$4,696

Operating Activities. The increase in our net cash used in operating activities of approximately $41.6 million during the nine months ended September 30, 2015 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 $97.2 million during the nine months ended September 30, 2015 was primarily a result of our $138.2 million net loss, offset by the add-back of non-cash expenses of $22.0 million for stock-based compensation, the amortization of investment premium of $4.5 million and net changes in operating assets and liabilities of $14.4 million. Net cash used in operating activities of $55.6 million during the nine months ended September 30, 2014 was primarily a result of our $248.4 million net loss, partially offset by the add-back of non-cash items of $16.5 million for share-based compensation, $170.8 million for warrant liability revaluation, $2.4 million for the amortization of investment premium and $2.9 million due to net changes in operating assets and liabilities.

Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2015 and 2014 was $414.3 million and $129.6 million, respectively. This net increase in cash used in investing activities of approximately $284.6 million is attributed to the increase in the purchases of investments of $363.9 million as a result of investing the proceeds from the February 2015 and April 2015 offerings, offset by the increase in the sale of investments of $81.0 million. The increase in purchases of equipment, improvements and furniture and fixtures of approximately $1.8 million is primarily related to our expansion efforts at our New York office and leasehold improvements in our United Kingdom office.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2015 were $564.4 million compared to $189.9 million for the comparable period in 2014. This increase was primarily the result of funds received through the February 2015 and the April 2015 offerings.

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. 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 operating as a public company and further plan on expanding 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. We anticipate that we will need substantial additional funding in connection with our continuing operations.

As of September 30, 2015, we had $695.7 million in cash, cash equivalents and investment securities. We anticipate that our adjusted operating expenses for the year ending December 31, 2015 will be below our previously provided guidance of $240 million, driven primarily by the timing of hiring of personnel, certain clinical trial and related expenses, market and medical research expenses and manufacturing related purchases for OCA. Adjusted operating expenses in 2015 are planned to support the clinical development program for OCA in PBC, NASH and PSC, the expansion of our clinical, regulatory, medical affairs and commercial infrastructure in the United States, Europe and other countries such as Canada, increased OCA manufacturing activities, as well as the continued development of INT-767 and other preclinical pipeline programs. The build out of our commercial infrastructure is on track with the recent hiring of the U.S. territory business managers and other field personnel in October 2015, and we are continuing our infrastructure expansion in clinical development, regulatory and medical affairs. We also anticipate that our adjusted operating expenses in 2016 will be higher than our adjusted operating expenses for 2015 to reflect the increase in headcount that occurred in the latter part of 2015 and anticipated increases in commercialization and research and development expenses. Accordingly, we will continue to require substantial additional capital to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialization of our products under development.

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 U.S. generally accepted accounting principles, or GAAP. Adjusted operating expense is a financial measure not calculated in accordance with GAAP. See “Non-GAAP Financial Measures” for more information.

We expect that our existing cash and cash equivalents will be sufficient to fund our operations and capital expenditure requirements beyond the end of 2016. However, 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. We currently plan to use our existing cash and cash equivalents to:

- expand our clinical, regulatory, medical affairs and commercial infrastructure in the United States and Europe;
- continue our clinical development of OCA in PBC, NASH and PSC;
- expand our OCA manufacturing activities;
- advance INT-767, including the completion of IND-enabling preclinical studies for INT-767 and the initiation of a Phase 1 clinical trial, and other preclinical pipeline programs; and
- prepare for and initiate the planned commercial launch of OCA in PBC in the United States, certain European countries and Canada in 2016.

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.

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

- the willingness of the FDA and the EMA to accept the POISE trial, which is our completed Phase 3 clinical trial for PBC, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for the review and marketing approval of OCA for PBC;
- the progress, costs, results and timing of our ongoing 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;
- the design of our overall Phase 3 program in NASH, which includes our recently initiated Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis and may include Phase 3 trials in other subpopulations with NASH such as those with cirrhosis;
- the progress, costs, results and timing of our recently initiated Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis, other supporting trials and studies necessary to support anticipated filings for marketing approval of OCA in non-cirrhotic NASH patients with liver fibrosis, including the sufficiency of one pivotal clinical trial for marketing approval or the acceptability of a surrogate endpoint for accelerated approval of OCA in this patient population, and any additional trials we may conduct in other subpopulations of NASH patients;
- the progress, costs, results of and timing of clinical development of OCA for other indications, including our Phase 2 trials of OCA in PSC and biliary atresia;
- the significant expansion of our operations, personnel and the size of our company and our need to continue to expand;
- 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 our product candidates in preclinical development, such as INT-767 and INT-777;
- the ability of our product candidates to progress through pre-clinical 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;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire 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 plan to expand our operations into Europe and other countries such as Canada and Australia and the manner in which we implement our expansion plan;
- 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 existing and expanding personnel; 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.

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 March 2, 2015.

In February 2015, we entered into an underlease with Merck Sharp & Dohme Limited for our new office in the King's Cross area of London, United Kingdom. The lease provides us with approximately 6,000 rentable square feet in London for office space. The lease term is anticipated to end in June 2019. The annual rent is £470,608, payable quarterly. We are also required to pay value added tax, or VAT, on the rent. We are responsible for a portion of the insurance, certain service charges and taxes for the building based on the floor area rented by us. As security for the underlease, we have provided the landlord with a rent deposit in the amount of £705,912 (or approximately $1.1 million), plus applicable VAT. The amount of the deposit may be reduced to £470,608 within 30 days after April 30, 2016 if there are no outstanding payments due and there are no material breaches of the underlease that have not been remedied in respect of which a drawdown notice has been served and has expired.

Off-Balance Sheet Arrangements

As of September 30, 2015, 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 March 2, 2015.

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 September 30, 2015, 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 September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

In 2013, the Committee of Sponsoring Organizations, or COSO, updated its 1992 *Internal Control – Integrated Framework* which is relied on to achieve compliance with the Sarbanes-Oxley Act. The new framework requires 17 principles of internal control to be present and functioning before an entity can assess that it has adequate control over financial reporting. We are implementing the 2013 COSO framework in 2015.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

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

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

The lawsuits allege that we made material misrepresentations and/or omissions of material fact in our public disclosures during the period from January 9, 2014 to January 10, 2014, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to our January 9, 2014 announcement that the FLINT trial had been stopped early based on a pre-defined interim efficacy analysis. Specifically, the lawsuits claim 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. 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 intend to file a sur-reply. The parties are currently undergoing discovery in relation to this matter.

The lead plaintiff seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees.

We believe that we have valid defenses to the claims in the lawsuit and intend to deny liability and defend ourselves vigorously. There can be no assurance, however, that we will be successful. At this time, no assessment can be made as to the likely outcome of this action or whether the outcome will be material to us. Therefore, we have not accrued for any loss contingencies related to this lawsuit.

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, 2014 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 OCA or any of our other product candidates will receive regulatory approval, and without regulatory approval we will not be able to market and commercialize our product candidates.

We are initially developing obeticholic acid, or OCA, for the treatment of patient populations with chronic liver and other diseases, with a current principal focus on primary biliary cirrhosis, or PBC, nonalcoholic steatohepatits, 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 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 and set a target date of February 29, 2016 to take action under the Prescription Drug User Fee Act, or PDUFA. We cannot be certain that our applications will be reviewed in a timely manner or approved. 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. Approvals may also be conditional upon the completion of one or more clinical trials. 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. 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. Also, regulatory approval for any of our product candidates may be withdrawn. 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 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, and we are finalizing other preclinical and clinical studies required to complete the filings. 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 intend to conduct a number of supporting studies and trials such as a Phase 2 trial characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. 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 Pharma Co., Ltd., or 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.

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. In PBC, although ursodiol is the standard of care, studies have shown that up to 50% of PBC patients fail to respond adequately to treatment, meaning that they continue to be at significant risk of progressing to liver failure even with treatment. 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 and set a target date of February 29, 2016 to take action under PDUFA. 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 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 are referred 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.

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 the trial in December 2014. There can be no assurance that our clinical outcomes confirmatory trial will confirm that the surrogate endpoints used for accelerated approval will eventually show an adequate correlation with clinical outcomes. If the clinical outcomes confirmatory trial fails to show such adequate correlation, we may not be able to maintain our previously granted marketing approval for OCA in PBC.

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) 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.

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 and set a target date of February 29, 2016 to take action under PDUFA. We cannot assure you that our POISE trial results will result in our receiving marketing approval for OCA in PBC or that our planned 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.

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 September 30, 2015 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 September 30, 2015, 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: November 9, 2015 By: /s/ Mark Pruzanski, M.D.
Mark Pruzanski
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2015 By: /s/ Barbara Duncan
Barbara Duncan
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit Index

Exhibit Number	Description of Exhibit
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 September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at September 30, 2015 (unaudited) and December 31, 2014, (ii) Condensed Consolidated Statements of Operations for the three and nine month periods ended September 30, 2015 and 2014 (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine month periods ended September 30, 2015 and 2014, (iv) Condensed Consolidated Statements of Cash Flows for the nine month periods ended September 30, 2015 and 2014 (unaudited) and (v) Notes to Condensed Consolidated Financial Statements (unaudited).