INTERCEPT PHARMACEUTICALS INC
Form 10-Q
August 11, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2014

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	**(I.R.S. Employer**

Incorporation or Organization)	**Identification Number)**
450 West 15th Street, Suite 505	**10011**
New York, NY	
(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¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of July 31, 2014, there were 21,217,959 shares of common stock, $0.001 par value per share, outstanding.

Intercept Pharmaceuticals, Inc.

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FORWARD-LOOKING STATEMENTS

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

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

- the 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, 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 collaborators’ election to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- 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;
- 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 the proceeds from our initial public offering in October 2012 and our follow-on public offerings of common stock in June 2013 and April 2014;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startup Act, or JOBS Act;
- our estimates regarding expenses, future revenues, capital requirements and the accuracy thereof; 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 this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2014, particularly in Item 1.A. Risk Factors. Those risk factors discuss risks and uncertainties that include, but not are limited to, the following: we will require substantial additional funding; OCA and/or our other product candidates may not receive regulatory approval in a timely manner or at all; we may be subject to delays in our clinical trials, which could result in increased costs and delays or limit our ability to obtain regulatory approval for our product candidates; the results of earlier studies and clinical trials of our product candidates may not be predictive of future clinical trial results, and our product candidates may not have favorable results in future clinical trials; even if approved, our product candidates may not be accepted by healthcare providers or healthcare payors; our collaborators could fail to perform their obligations under our collaboration agreements; and we may not be able to maintain and protect our intellectual property assets. 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.

PART I

Item 1. FINANCIAL STATEMENTS

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

	December 31, 2013 (Audited)	June 30, 2014 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$13,363,185	$44,961,233
Investment securities, available-for-sale	131,468,797	254,069,441
Prepaid expenses and other current assets	2,732,556	7,617,610
Total current assets	147,564,538	306,648,284
Fixed assets, net	1,672,295	2,163,449
Security deposits	1,081,747	1,957,034
Total assets	$150,318,580	$310,768,767
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$7,259,805	$10,138,885
Short-term portion of deferred revenue	1,621,622	1,781,620
Total current liabilities	8,881,427	11,920,505
Long-term liabilities:		
Long-term portion of deferred revenue	8,918,916	8,908,111
Long-term portion of warrant liability	50,112,137	-
Total liabilities	67,912,480	20,828,616
Stockholders' equity:		
Common stock. 25,000,000 shares authorized; 19,389,610, and 21,178,730 shares issued and outstanding as of December 31, 2013 and June 30, 2014, respectively; par value $0.001 per share	19,390	21,179
Additional paid-in capital	268,302,617	688,486,472
Accumulated other comprehensive income (loss), net	59,853	(33,137)
Accumulated deficit	(185,975,760)	(398,534,363)
Total stockholders' equity	82,406,100	289,940,151
Total liabilities and stockholders' equity	$150,318,580	$310,768,767

See accompanying notes to the condensed consolidated financial statements.

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INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2014	2013	2014
Licensing revenue	$405,407	$445,405	$810,812	$850,808
Costs and expenses:				
Research and development	5,132,971	14,919,190	9,965,527	29,211,883
General and administrative	2,890,505	7,954,903	5,287,359	13,606,030
Total costs and expenses	8,023,476	22,874,093	15,252,886	42,817,913
Other income (expense):				
Revaluation of warrants	(5,572,081)	55,794,796	(9,254,586)	(170,831,872)
Other income (loss), net	(286,767)	104,117	9,595	240,374
	(5,858,848)	55,898,913	(9,244,991)	(170,591,498)
Net income (loss)	$(13,476,917)	$33,470,225	$(23,687,065)	$(212,558,603)
Net income (loss) per share:				
Basic	$(0.79)	$1.60	$(1.41)	$(10.50)
Diluted	$(0.79)	$1.51	$(1.41)	$(10.50)
Weighted average shares outstanding:				
Basic	16,970,519	20,965,094	16,765,464	20,238,955
Diluted	16,970,519	22,204,934	16,765,464	20,238,955

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Income (Loss)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2014	2013	2014
Net income (loss)	$(13,476,917)	$33,470,225	$(23,687,065)	$(212,558,603)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities:				
Unrealized holding gains (losses) arising during the period	136,190	(79,131)	(87,840)	(97,098)
Reclassification for recognized gains on marketable investment securities during the period	-	2,509	-	4,108
Net unrealized gains (losses) on marketable investment securities	$136,190	$(76,622)	$(87,840)	$(92,990)
Comprehensive income (loss)	$(13,340,727)	$33,393,603	$(23,774,905)	$(212,651,593)

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2013	2014
Cash flows from operating activities:		
Net loss	$(23,687,065)	$(212,558,603)
Adjustments to reconcile net loss to net cash used in operating activities:		
Revaluation of warrants	9,254,586	170,831,872
Share-based compensation	3,497,452	11,230,262
Depreciation	52,484	130,413
Amortization of investment premium	528,463	1,370,468
Changes in:		
Prepaid expenses, other current assets and security deposits	95,115	(5,760,341)
Accounts payable, accrued expenses and other current liabilities	(74,078)	2,879,080
Deferred revenue	(810,812)	149,193
Net cash used in operating activities	(11,143,855)	(31,727,656)
Cash flows from investing activities:		
Purchases of investment securities	(59,782,263)	(161,351,747)
Sales of investment securities	13,997,188	37,287,646
Purchases of equipment, improvements, and furniture and fixtures	(39,857)	(621,567)
Net cash used in investing activities	(45,824,932)	(124,685,668)
Cash flows from financing activities:		
Proceeds from issuance of stock offerings, net of issuance costs	61,379,263	183,545,563
Proceeds from exercise of options	2,210,752	4,465,809
Proceeds from exercise of warrants	8,101	-
Net cash provided by financing activities	63,598,116	188,011,372
Net increase in cash and cash equivalents	6,629,329	31,598,048
Cash and cash equivalents – beginning of period	45,511,641	13,363,185
Cash and cash equivalents – end of period	$52,140,970	$44,961,233
Supplemental disclosures of noncash activities:		
Issuance of common stock for cashless warrant exchange	$6,935,368	$220,944,009

See accompanying notes to the condensed consolidated financial statements.

Notes to Condensed Consolidated Financial Statements (unaudited)

1.*Overview of Business*

Intercept Pharmaceuticals, Inc. (“Intercept” or the “Company”), is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver and intestinal diseases utilizing its proprietary bile acid chemistry. 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 an office in San Diego, California. The Company has a wholly owned subsidiary in Italy which acts as the Company’s legal representative for its clinical trials in the European Union to satisfy European Union regulatory requirements. Intercept was incorporated in Delaware in September 2002.

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited. The condensed unaudited consolidated financial statements have been prepared in accordance with GAAP on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company’s financial position, results of operations and cash flows for the dates and periods presented herein. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes set forth in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2014. The results for the three and six months ended June 30, 2013 and June 30, 2014 (unaudited) are not necessarily indicative of results to be expected for the year ending December 31, 2014, any other interim periods or any future year or period. The June 30, 2014 condensed consolidated financial statements reflect the adoption of Accounting Standard Update (ASU) No. 2014-10, *Development Stage Entities (Topic 915) – Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation,* which no longer requires inception to date information.

Use of Estimates

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

Revision of Prior Period Financial Statements

During the second quarter of 2014, management identified a misstatement representing an overstatement of non-cash share-based compensation expense in the first quarter of 2014 of approximately $11.6 million related to the valuation of non-employee options. Management determined that the effect of the share-based compensation expense overstatement was not material to the financial statements for the prior interim period. In order to correct the error, in accordance with the SEC's Staff Accounting Bulletin No. 108 ("SAB 108"), the Company recorded the following immaterial corrections to the financial statements for the three months ended March 31, 2014, which are reflected in our results for the six months ended June 30, 2014: (a) a decrease in additional paid-in-capital of $11.6 million and a decrease in accumulated deficit of $11.6 million, which in total has no impact on shareholders' deficit; and (b) a decrease of $11.6 million in research and development expenses and a corresponding decrease in net loss.

2. 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) and agreed not to commercialize other farnesoid X receptor, or FXR, agonist compounds or products for PBC, NASH or specified additional indications in countries in which Sumitomo Dainippon retains an exclusive license to OCA under the agreement. 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 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. The sales milestones are based on aggregate sales amounts of OCA 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. 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. 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 exclusive 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.

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 the Korea option are being recognized ratably over this period. During the three months ended June 30, 2013 and 2014, the Company recorded revenue of approximately $406,000 and $445,000, respectively, and during the six months ended June 30, 2013 and 2014, the Company recorded revenue of approximately $811,000 and $851,000, respectively, in "Licensing Revenue" in its Consolidated Statement of Operations for the Company's efforts under the agreement. The Company has not achieved any of the milestones relating to the agreement as of June 30, 2014 and has not recognized any revenue related to such milestones. The Company has determined that each potential future development, regulatory and sales milestone is substantive.

3. Investments

The following table summarizes the Company's cash, cash equivalents and investments as of December 31, 2013 and June 30, 2014:

	As of December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$13,363	$ -	$ -	$13,363
Investment securities:				
Commercial paper	7,993	1	-	7,994
Corporate debt securities	115,704	115	(59)	115,760
Municipal securities	1,051	1	-	1,052
U.S. government and agency securities	6,657	6	-	6,663
Total investments	131,405	123	(59)	131,469
Total cash, cash equivalents and investments	$144,768	$ 123	$ (59)	$144,832

	As of June 30, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$44,961	$ -	$ -	$44,961
Investment securities:				
Commercial paper	18,986	-	(6)	18,980
Corporate debt securities	221,019	135	(156)	220,998
U.S. government and agency securities	14,095	3	(7)	14,091
Total investments	254,100	138	(169)	254,069
Total cash, cash equivalents and investments	$299,061	$ 138	$ (169)	$299,030

The following table shows the gross unrealized losses and fair value of the Company's available-for-sale investments aggregated by investment category and length of time that individual securities have been in the position:

	As of December 31, 2013					
	Less than 12 months		12 Months or greater		Total	
	(In thousands)					
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Corporate debt securities	$9,515	$ (2)	$ 31,312	$ (57)	$40,827	$ (59)
Total	$9,515	$ (2)	$ 31,312	$ (57)	$40,827	$ (59)

	As of June 30, 2014					
	Less than 12 months		12 Months or greater		Total	
	(In thousands)					
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Corporate debt securities	$32,059	$ (18)	$ 97,084	$ (138)	$129,143	$ (156)
Commercial paper	15,981	(6)			15,981	(6)
U.S. government and agency securities	-	-	8,992	(7)	8,992	(7)
Total	$48,040	$ (24)	$ 106,076	$ (145)	$154,116	$ (169)

4. Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. A valuation allowance is established against net deferred

tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be resolved. The effect of a change in tax rates or laws on deferred tax assets and deferred tax liabilities is recognized in operations in the period that includes the enactment date of the rate change.

The deferred tax asset or liability represents future tax return consequences of those differences, which will be taxable when the assets and liabilities are recovered or settled. The provision for income taxes may differ from the actual expense that would result from applying the federal statutory rate to income before taxes because certain income for financial reporting purposes is not taxable and certain expenses for financial reporting purposes are not deductible for tax purposes. At December 31, 2013 and June 30, 2014, the Company had available net operating loss carryforwards to reduce future taxable income of approximately $108.2 million and $144.3 million, respectively, for tax reporting purposes. These carryforwards expire between 2024 and 2032. 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 combined federal, state and city deferred tax asset of approximately $60.2 million and $75.8 million at December 31, 2013 and June 30, 2014, respectively, resulted from the tax effects of net operating losses and differences between the book and tax bases for the share-based compensation and depreciation. 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 tax asset. As a result, the Company has not recorded any income tax benefit since its inception.

5. Warrants to Purchase Common Stock

In conjunction with various financing transactions, the Company issued warrants to purchase the Company's common stock. Certain of the warrants included a so-called "down round" provision that provided for a reduction in the warrant exercise price if there were subsequent issuances of additional shares of common stock for consideration per share less than the per share warrant exercise prices and the remaining warrants contained a provision that required the underlying shares to be registered upon an IPO. These warrants were deemed to be derivative instruments and as such, recorded as a liability and are 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 the values determined using a binomial valuation model. The estimates in the Black-Scholes option-pricing model and the binomial valuation model are 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, and could differ materially in the future. Changes in the fair value of the common stock warrant liability from the prior period are 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. The Company recorded a

final non-cash warrant revaluation adjustment to other income of approximately $55.8 million for the three month period ended June 30, 2014.

6. Fair Value Measurements

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

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

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

- Pricing Models with Significant Observable Inputs — The fair value of an asset or liability is based on information derived from either an active market quoted price, which may require further adjustment based on the attributes of the financial asset or liability being measured, or an inactive market transaction (Level 2).

- Pricing Models with Significant Unobservable Inputs — The fair value of an asset or liability is primarily based on internally derived assumptions surrounding the timing and amount of expected cash flows for the financial instrument. Therefore, these assumptions are unobservable in either an active or inactive market (Level 3).

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

The Company's cash deposits and money market funds are classified within Level 1 of the fair value hierarchy because they are valued using bank balances or quoted market prices. Investments are classified as Level 2 instruments based on market pricing or other observable inputs. None of the Company's investments are classified within Level 3 of the fair value hierarchy. The Company's warrant liability has been valued pursuant to the discussion in note 5 above and thus is included in Level 3.

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

		Fair Value Measurements Using		
	Total	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(In thousands)			
December 31, 2013				
Assets:				
Money market funds	$8,216	$8,216	$ -	$ -
Available for sale securities:				-
Commercial paper	7,994	-	7,994	$ -
Corporate debt securities	115,760	-	115,760	-
U.S. government and agency securities	6,663	-	6,663	-
Municipal securities	1,052	-	1,052	-
Total financial assets:	$139,685	$8,216	$ 131,469	$ -
Liabilities:				
Warrants to purchase common stock	$(50,112)	$-	$ -	$ (50,112)
Total financial liabilities	$(50,112)	$-	$ -	$ (50,112)
June 30, 2014				
Assets:				
Money market funds	$32,666	$32,666	$ -	$ -
Available for sale securities:				
Commercial paper	18,980	-	18,980	-
Corporate debt securities	220,998	-	220,998	-
U.S. government and agency securities	14,091	-	14,091	-
Total financial assets:	$286,735	$32,666	$ 254,069	$ -

Level 3 Valuation

Financial assets or liabilities are considered Level 3 when their fair values are determined using models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable. The following table provides a summary of the changes in fair value of the Company's financial liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during the six-month period ended June 30, 2014.

	Warrant Liability (In thousands)
Level 3	
Balance at December 31, 2013	$ 50,112
Net losses recognized in earnings	170,832
Exercises	(220,944)
Balance at June 30, 2014	$ -

The Company determined the fair value of its warrant liability based on the Black-Scholes pricing model based on the Company's stock price at the measurement date, exercise price of the warrant, risk free interest rate and historical volatility. The estimated fair value of marketable debt securities (commercial paper, corporate debt securities, U.S. government and agency securities and municipal securities), by contractual maturity, are as follows:

	Fair Value as of December 31, 2013	June 30, 2014
	(In thousands)	
Due in one year or less	$ 56,044	$ 123,805
Due after one year through 2 years	75,425	130,264
Total investments in debt securities	$ 131,469	$ 254,069

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

7. Stockholders' Equity

Common Stock

In October 2012, the Company completed the initial public offering (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 estimated offering expenses payable by the Company. Upon the closing of the IPO, all outstanding shares of the Company's preferred stock (described below) 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 at a public offering price of $33.01 per share. The shares were registered pursuant to a registration statement on Form S-1. Net proceeds were approximately $61.2 million, after deducting underwriting discounts and commission and offering expenses payable 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, at a public offering price of $320.00 per share. The shares were registered pursuant to a registration statement on Form S-3. After underwriting discounts and commissions and estimated 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.

Dividends

The holders of common stock are entitled to receive dividends from time to time as declared by the Board of Directors.

Authorized Shares

As of June 30, 2014, the Company was authorized to issue 25,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of preferred stock, $0.001 par value per share. At the 2014 annual meeting of stockholders held on July 17, 2014, the Company's stockholders approved an amendment to the Company's restated certificate of incorporation to increase the number of authorized shares of common stock from 25,000,000 shares to 35,000,000 shares.

8. Share-Based Compensation

The compensation expense related to the Company's share-based compensation arrangements has been included in the condensed consolidated statement of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2014	2013	2014
	(In thousands)			
General and administrative	$981	$2,322	$1,926	$3,821
Research and development	909	1,473	1,571	7,409
Total share-based compensation	$1,890	$3,795	$3,497	$11,230

The following table summarizes stock option activity during the six months ended June 30, 2014:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2013	1,524,837	$ 21.32

Granted	217,836	$ 256.36
Exercised	(284,997)	$ 15.23
Forfeited	(3,029)	$ 21.50
Outstanding, June 30, 2014	1,454,647	$ 57.71
Exercisable, June 30, 2014	722,183	$ 14.32

In April 2014, the Company issued 57,063 performance-based options to certain executives to purchase common stock that will vest upon the achievement of certain regulatory milestones related to OCA at future dates. As of June 30, 2014, the achievement of the milestones was not deemed to be probable and no share-based compensation expense was recognized for these options.

During the three months ended June 30, 2014, the Company granted 31,892 restricted stock awards (RSA) that vest over a four year period. The fair value of the RSAs is established based on the closing price of the Company’s common stock on the date of the RSA grant. For the six months ended June 30, 2013 and 2014, share-based compensation expense related to previously granted restricted stock units (RSU) and the newly granted RSA awards was approximately $1.1 million and $1.7 million, respectively. For the three months ended June 30, 2013 and 2014, the share-based compensation expense related to RSU and RSA awards was approximately $300,000 and $1.0 million, respectively. The following table summarizes the aggregate restricted stock (RSU and RSA) activity:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding, December 31, 2013	121,069	$ 25.30
Granted	31,892	$ 257.23
Exercised	(37,473)	$ 34.29
Outstanding, June 30, 2014	115,488	$ 97.20

9. Net Income (Loss) Per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2014	2013	2014
	(In thousands, except share and per share amounts)			
Historical net income (loss) per share				
Numerator:				
Net income (loss) attributable to common stockholders	$(13,477)	$33,470	$(23,687)	$(212,559)
Denominator:				
Weighted average shares used in calculating net income (loss) per share - basic	16,970,519	20,965,094	16,765,464	20,238,955
Dilutive effect of equity incentive plans' shares	-	1,239,840	-	-
Weighted average shares used in calculating net income (loss) per share - dilutive	16,970,519	22,204,934	16,765,464	20,238,955
Net income (loss) per share:				
Basic	$(0.79)	$1.60	$(1.41)	$(10.50)
Diluted	$(0.79)	$1.51	$(1.41)	$(10.50)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2014	2013	2014
	(In thousands)			
Options	1,717	182	1,717	1,455
Warrants to purchase common stock	911	-	911	-
Restricted stock units	144	-	144	84
Total	2,772	182	2,772	1,539

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

Additional complaints may be filed against the Company and its directors and officers related to its disclosures.

The Company believes that this lawsuit is without merit. 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.

11. Recent Accounting Pronouncements

In June, 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update (ASU) No. 2014-10, *Development Stage Entities (Topic 915) – Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation* which eliminates the concept of a development stage entity (DSE*)* in its entirety from current accounting guidance. Previous reporting requirements for a DSE, including inception-to-date information, will no longer apply. For public business entities, the amendments to ASU 2014-10 are effective prospectively for annual reporting periods beginning after December 15, 2014, and interim periods within those annual periods. Early application of each of the amendments is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued (public business entities) or made available for issuance (other entities). The June 30, 2014 financial statements reflect the early adoption of the accounting standard.

In June, 2014, the FASB issued ASU No. 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could be Achieved after the Requisite Service Period.* This amendment requires that a performance target that affects vesting and that could be achieved after the requisite service period should be treated as a performance condition. This amendment is effective for annual periods and interim periods within those annual periods beginning after December 15, 2014. The Company is currently evaluating the impact of this amendment.

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, 2013 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2014. 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 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 liver and intestinal diseases with high unmet need utilizing our proprietary bile acid chemistry. Our product candidates have the potential to treat orphan and more prevalent liver diseases for which there currently are limited therapeutic solutions.

Our lead product candidate, obeticholic acid, or OCA, is a bile acid analog, or a chemical substance that has a structure based on a naturally occurring human bile acid. OCA is a first-in-class product candidate that selectively binds to and induces activity in the farnesoid X receptor, or FXR, which we believe has broad liver-protective properties. We are developing OCA initially for primary biliary cirrhosis, or PBC, as a second line treatment for patients who have an inadequate response to or who are unable to tolerate standard of care therapy and therefore need additional treatment. PBC is a chronic autoimmune liver disease that, if inadequately treated, may eventually lead to cirrhosis, liver failure and death. In March 2014, we completed a Phase 3 clinical trial of OCA in PBC, which we call the POISE trial, that we anticipate will serve as the basis for seeking the first regulatory approval to market OCA in the United States and Europe. OCA has been granted Fast Track designation by the U.S. Food and Drug Administration, or FDA, for the treatment of patients with PBC. We expect to complete our filings for marketing approval of OCA in PBC in the United States and Europe during the first half of 2015. We also anticipate finalizing the protocol for our clinical outcomes confirmatory trial in PBC during the third quarter of 2014 and initiating the trial around year end 2014.

OCA is also currently being evaluated in a Phase 2b trial for the treatment of nonalcoholic steatohepatitis, or NASH, known as the FLINT trial, which has been sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health. In January 2014, the NIDDK stopped the double-blind treatment phase of the FLINT trial early following a planned interim analysis showing that OCA had met

the primary efficacy endpoint of the trial based on a pre-defined interim efficacy criteria. The NIDDK's decision to stop the FLINT treatment phase early was based primarily on OCA having met the efficacy criterion, while also being informed by the risks involved in continuing to perform liver biopsies in the remaining patients and the available safety data from the trial with respect to disproportionate lipid abnormalities and the occurrence of cardiovascular events in the OCA treatment arm. We recently received from NIDDK a draft manuscript decribing the results from the FLINT trial. See "Recent Developments."

In addition to PBC and NASH, we are developing OCA in other patient populations, including cirrhosis, primary sclerosing cholangitis, or PSC, portal hypertension, alcoholic hepatitis and bile acid diarrhea and anticipate initiating a Phase 2 clinical trial for PSC at the end of 2014. Furthermore, we plan to complete IND-enabling studies in INT-767, an earlier stage product for which we plan to initiate a Phase 1 trial in the first half of 2015. OCA has received orphan drug designation in the United States and Europe for the treatment of PBC and PSC. We own worldwide rights to OCA outside of Japan, China and Korea, where we have exclusively licensed the compound to Sumitomo Dainippon Pharma, or Sumitomo Dainippon, and granted it an option to exclusively license OCA in certain other Asian countries.

In April 2014, we completed a follow-on public offering of 1,000,000 shares of our common stock, of which 600,000 shares were sold by us and 400,000 shares were sold by certain selling stockholders, at a public offering price of $320.00 per share. After underwriting discounts and commissions and estimated offering expenses, we received net proceeds from the offering of approximately $183.5 million. We did not receive any proceeds from the sale of shares of common stock by the selling stockholders. Our common stock trades on the NASDAQ Global Select Market, or NASDAQ, under the trading symbol "ICPT."

Our net loss for the three months ended June 30, 2013 was approximately $13.5 million, while our net income for the three months ended June 30, 2014 was approximately $33.5 million. Our net losses for the six months ended June 30, 2013 and 2014 were $23.7 million and $212.6 million, respectively. Substantially all of our net loss resulted from costs incurred in connection with our research and development programs, general and administrative costs associated with our operations and the mark-to-market of our liability-classified warrants. Our net income in the second quarter of 2014 is primarily attributable to the revaluation of our warrants, partially offset by operating costs.

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, NASH, PSC and other patient populations;

- seek to obtain regulatory approvals for OCA for PBC, NASH, PSC and other potential patient populations;
- outsource the commercial manufacturing of OCA for any indications for which we receive regulatory approval;
- engage in activities relating to the sales, marketing and distribution of OCA for any indications for which we may receive regulatory approval;
- continue research and development efforts with our preclinical development compounds, such as INT-767, whether independently or with a third-party collaborator;
- maintain, expand and protect our intellectual property portfolio;
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and
- operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital prior to the commercialization of OCA or any of our other product 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 administrative headquarters in New York, New York and an office in San Diego, California. We have a wholly-owned subsidiary in Italy which acts as our legal representative for our clinical trials in the European Union to satisfy European Union regulatory requirements.

Recent Developments

NIDDK recently provided us with a draft manuscript intended for publication that describes the results from the FLINT trial. This trial was a double blind, placebo-controlled trial of a once-daily dose of 25mg of OCA or placebo given for 72 weeks in 283 patients with biopsy-proven NASH. The draft manuscript presents histological data from the primary intention-to-treat population comprised of the 219 patients who were eligible for a repeat biopsy after completing the 72-week treatment phase of the trial and non-histological secondary endpoints from all patients who went on to complete the post-treatment follow-up visit which took place 24 weeks after the conclusion of the treatment phase. For purposes of this trial, p-values of 0.05 or lower indicated statistical significance. As the manuscript is in draft form and is expected to undergo peer review, it is subject to further modification prior to publication. The top-line information about the FLINT trial results described below is based on the draft manuscript provided to us by NIDDK.

Primary Endpoint

The proportion of patients meeting the FLINT primary histological endpoint, defined as a decrease in the NAFLD Activity Score (NAS) of at least two points with no worsening of fibrosis, was 46% in the OCA treatment group and 21% in the placebo treatment group ($p < 0.001$, n=219). Subgroup analyses showed a numerically higher response rate in OCA-treated patients with more advanced NASH, as assessed by NAS, fibrosis staging or co-morbid type 2 diabetes. The mean pre-treatment baseline NAS for patients in the OCA treatment group was 5.3 of a total possible score of 8 (comprised of hepatocellular ballooning 0 – 2, lobular inflammation 0 – 3 and steatosis 0 – 3).

Secondary Efficacy Endpoints

More patients in the OCA treatment group also experienced improvements in the following histological secondary endpoints (n=200):

- All the individual components of NAS improved in OCA-treated patients (p-values ranged from 0.03 to <0.001 for each component vs. placebo);
- NASH resolution: 22% of OCA-treated patients vs. 13% of patients on placebo (p=0.09); and
- Fibrosis improvement (scored 0 – 4): 35% of OCA-treated patients vs. 19% of patients on placebo (p=0.01);
  - Decrease in mean value of 0.2 from a baseline mean of 1.9 in OCA-treated patients vs. increase in mean value of 0.1 from baseline mean of 1.8 in patients on placebo (p=0.01).

Portal inflammation, which is not a component of the NAS and is typically mild in adult NASH patients, was also assessed as a secondary histological endpoint. There was essentially no improvement in portal inflammation with no difference observed between the two groups (12% of OCA patients vs. 13% of placebo patients (p=0.76)).

The histological improvements observed in OCA-treated patients versus placebo were accompanied by significant reductions in the serum liver enzymes alanine aminotransferase (ALT), aspartate aminotransferase (AST) and gamma-glutamyl transferase (GGT), each of which had been abnormally elevated at the time of treatment initiation. A modest but statistically significant decrease in bilirubin and increase in alkaline phosphatase (ALP) were also observed, both remaining within typical normal limits. These five biochemical parameters tended to return to pre-treatment values at the end of the 24-week follow-up phase after the stopping of OCA treatment. The changes in serum liver enzymes observed in FLINT patients on OCA were generally consistent with results observed in a previously published, six week trial in diabetic patients with non-alcoholic fatty liver disease, or NAFLD [Mudaliar S, Gastroenterology 2013; 145; 574-582].

Metabolic Parameters

OCA treatment was associated with the following changes in metabolic parameters at 72-weeks (n=257).

- Statistically significant weight loss in patients on OCA treatment compared to patients in the placebo group (p=0.008);
- Increase in a marker of fasting hepatic insulin resistance, HOMA-IR, in the OCA treatment group (p=0.01), although an even larger increase was observed in the placebo group at the conclusion of the 24-week follow-up phase; and
- No changes in hemoglobin A1c, a measure of average blood sugar control over a period of approximately three months, in either OCA or placebo groups.

Serum Lipids

OCA treatment was associated with changes in serum lipid levels that were observed within 12 weeks of initiating treatment (the first time point assessed), then decreased in magnitude while on treatment and effectively returned to baseline during the 24-week post-treatment period:

	Lipid Parameter (mg/dL, mean values)							
	Total Cholesterol		**HDL Cholesterol**		**LDL Cholesterol**		**Triglycerides**	
Time Period	**OCA**	**Pbo**	**OCA**	**Pbo**	**OCA**	**Pbo**	**OCA**	**Pbo**
Baseline (n=283)	190	187	42	44	112	111	196	178
Change from baseline to 72 weeks (n=257)	*+6**	*-7**	*-1**	*+1**	*+9**	*-8**	*-20*	*-7*
Change from baseline to 96 weeks (n=240)	*-12*	*-8*	*+1*	*+1*	*-12*	*-12*	*-3*	*0*

* P-value ≤ 0.01 for OCA vs. placebo comparison

Safety and Tolerability

The draft FLINT manuscript reported that OCA was generally well tolerated based on the safety and tolerability data from all 283 patients randomized in the trial. The incidence of adverse events in the OCA and placebo treatment groups was similar for all symptoms except pruritus, which occurred more frequently (23% vs. 6%, p<0.001) and at a higher grade (predominantly moderate pruritus). One patient discontinued due to pruritus in the OCA treatment arm.

The incidence of severe or life threatening events was not different between the two treatment groups and most of the events in both groups were deemed to be unrelated to treatment, including all severe or life threatening cardiovascular events. There were two patient deaths in the trial that were previously disclosed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2014; neither death was considered related to OCA treatment.

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. In March 2011, we entered into an exclusive licensing agreement with Sumitomo Dainippon for the development of OCA in Japan and China. Under the terms of the agreement, we received an up-front payment of $15.0 million and may be eligible to receive up to approximately $300 million in additional payments for development, regulatory and commercial sales milestones for OCA in Japan and China. In May 2014, Sumitomo Dainippon exercised its option under the license agreement to add Korea as part of its licensed territories and paid us a $1.0 million up-front fee. For accounting purposes, the up-front payments are recorded as deferred revenue and amortized over time. For the six months ended June 30, 2014, we recognized approximately $851,000 in license revenue for amortization of the up-front payments. We anticipate that we will recognize revenue of approximately $1.8 million per year through 2020, the expected end of the development period, for the amortization of the up-front payments from Sumitomo Dainippon.

In the future, we may generate revenue from a combination of license fees and other upfront payments, research and development payments, milestone payments, product sales and royalties in connection with strategic alliances. 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 strategic alliance partners. If our strategic alliance 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:

- salaries and related overhead expenses for personnel in research and development functions;
- fees paid to consultants and clinical research organizations, or CROs, including in connection with our preclinical and clinical trials, and other related clinical trial 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 acquiring and manufacturing clinical trial materials;
- depreciation of leasehold improvements, laboratory equipment and computers;
- costs related to compliance with regulatory requirements; and
- costs related to stock options or other share-based compensation granted to personnel in research and development functions.

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. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, in connection with our clinical trials, and costs related to acquiring and manufacturing clinical trial materials. We have been developing OCA and other FXR agonists, as well as TGR5 agonists, and typically use our employee and infrastructure resources across multiple research and development programs. We do not allocate salaries, share-based compensation, employee benefit or other indirect costs related to our research and development function to specific product candidates. Those expenses are included in “Personnel costs” and “Indirect research and development expense” in the table below.

	Six Months Ended June 30,	
	2013	2014
	(In thousands)	
Direct research and development expense by program:		
OCA	$ 5,625	$ 14,924
INT-767	255	869
INT-777	45	-
Total direct research and development expense	5,925	15,793

Personnel costs (1)	3,703	12,023
Indirect research and development expense	337	1,396
Total research and development expense	$ 9,965	$ 29,212

(1) Personnel costs include stock options, restricted stock units, restricted stock awards and performance-based options granted to employees and non-employees with an associated share-based compensation expense of $1.6 million and $7.4 million for the six months ended June 30, 2013 and 2014, respectively. During the six months ended June 30, 2014, we added 20 research and development personnel.

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 are focused on our ongoing and planned clinical and preclinical studies and the other work we plan to undertake to support our New Drug Application, or NDA, and Marketing Authorization Application, or MAA, filings for OCA for the treatment of PBC, which we currently plan to complete by the first half of 2015. We have incurred and expect to continue to incur significant expenses in connection with these efforts, including:

- We completed our Phase 3 POISE trial of OCA in patients with PBC in March 2014 and expect to continue the LTSE phase of the trial through 2019.
- We are currently in discussions with the FDA on the clinical outcomes trial for OCA in PBC that must be underway at the time the FDA makes a decision whether to grant accelerated approval. We expect that the clinical outcomes trial will be completed on a post-marketing basis. We currently anticipate finalizing the protocol for this trial during the third quarter of 2014 and initiating this trial around year end 2014.
- We plan to conduct a Phase 1 clinical trial in healthy volunteers to evaluate the effect of OCA on the heart's electrical cycle, known as the QT interval, and are conducting or plan to conduct additional Phase 1 clinical trials in 2014.
- We have contracted 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 are working to secure second manufacturers.
- We are currently reviewing potential third-party manufacturers for our commercial supply of OCA and plan to begin building commercial supplies, including supplies of the starting material for manufacturing OCA, in 2014.
- We have contracted with and plan to engage a number of consultants in relation to our seeking of regulatory approval and intend to implement various electronic software and systems in relation to our regulatory activities.

In addition, we are evaluating OCA in other chronic liver and other intestinal diseases. Pending our detailed review of the FLINT trial results and discussions with the FDA and European Medicines Agency, or EMA, we plan to initiate our Phase 3 clinical program in NASH during the first half of 2015. In the meantime, we intend to initiate a Phase 2 trial investigating the lipid metabolic effects of OCA in NASH patients in the first half of 2015 and are evaluating whether to initiate a Phase 2 trial of OCA in pediatric NASH patients in the first half of 2015. For PSC, we intend to initiate a Phase 2 clinical trial at the end of 2014.

INT-767 and INT-777

We intend to continue to develop INT-767 (a dual FXR/TGR5 agonist) and INT-777 (pure TGR5 agonist), our two existing compounds not included in our collaboration with Servier to discover and develop additional novel TGR5 agonists. Currently, we plan to continue with preclinical development of INT-767 through to the filing of an Investigational New Drug, or IND, application and, subject to the IND application becoming effective, initiate a Phase 1 trial of INT-767 in healthy volunteers in the first half of 2015. We intend to continue development of INT-777 through potential collaborations with third parties over the next several years.

Other than OCA, our product development programs are at an early stage, 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, operational, finance and human resources functions. Other significant general and administrative expenses include OCA pre-commercial activities, facilities costs, accounting and legal services, stock compensation, information technology, professional fees for directors, travel 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 believe that these increases will likely include increased costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We have also incurred and may continue to incur increased costs to comply with corporate governance, internal controls and similar requirements applicable to public companies. In 2014, we anticipate that we will also implement a number of software, systems and other infrastructural changes in relation to our operations as a public company. During the six months ended June 30, 2014, we added 21 corporate and commercial personnel.

Other Income (Loss), Net

Other income (loss), net consists of interest income earned on our cash, cash equivalents and investment securities offset by management fees, capital base, franchise and real estate taxes. We expect interest income to increase in future periods as we invest the proceeds from our equity financings.

Revaluation of Warrants

In conjunction with various financing transactions, 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 2013 and 2014 included a provision that provides 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, including the warrants held by Genextra S.p.A., were deemed to be derivative instruments and as such, were recorded as a liability and marked-to-market at each reporting period. Certain other warrants outstanding during the first quarter of 2013 included a provision that required the shares underlying the warrants to be registered upon the completion of an initial public offering. As a result, these warrants were reclassified as a liability as of the date of our initial public offering and were also marked-to-market at each reporting date since the offering. 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 is recorded as a component of other income and expense.

Results of Operations

Comparison of the Three Months Ended June 30, 2013 and June 30, 2014

The following table summarizes our results of operations for each of the three months ended June 30, 2013 and 2014, together with the changes in those items in dollars:

	Three Months Ended June 30,		Dollar Change
	2013	2014	
	(In thousands)		
Licensing revenue	$405	$445	$ 40

Operating expenses:			
Research and development	5,133	14,919	9,786
General and administrative	2,891	7,955	5,064
Loss from operations	(7,619)	(22,429)	(14,810)
Warrant revaluation income (expense)	(5,572)	55,795	61,367
Other income (loss), net	(287)	104	391
Net loss	$(13,478)	$33,470	$ 46,948

Licensing Revenue

Licensing revenue was $405,000 and $445,000 for the three months ended June 30, 2013 and 2014, respectively, resulting from the amortization of the up-front payments from the collaboration agreements entered into with Sumitomo Dainippon.

Research and Development Expenses

Research and development expenses were $5.1 million and $14.9 million for the three months ended June 30, 2013 and 2014, respectively, representing an increase of $9.8 million. This increase in research and development expense primarily reflects:

- increased direct development expense for activities around our development program for OCA, including manufacturing of drug supply to support clinical trials of OCA and preparation of the NDA and MAA filings for PBC, of approximately $5.4 million;
- increased product development costs of $1.9 million;
- an increase in personnel on our development team to manage the increased activities around our development program for OCA, resulting in increased compensation and related benefits expense of approximately $1.5 million;

- increased non-cash share-based compensation expense of approximately $564,000, primarily related to the re-measurement of previously granted options to consultants; and
- increased indirect costs of approximately $515,000 primarily due to increased office related expenses of approximately $171,000, increased travel related costs of $174,000 and increased patent costs of $48,000.

General and Administrative Expenses

General and administrative expenses were $2.9 million and $8.0 million in the three months ended June 30, 2013 and 2014, respectively. The $5.1 million increase primarily reflects:

- an increase in non-cash share-based compensation expense of approximately $1.3 million due to an increase in our headcount;
- increased pre-commercial activities, including an increase in personnel resulting in increased compensation and related benefits expense, of approximately $1.4 million;
- an increase in personnel to manage increased activities due to our expanding operations, resulting in increased compensation and related benefits expense of approximately $1.3 million;
- increased legal expenses of approximately $248,000;
- increased office-related expenses of approximately $268,000; and
- increased rent and utilities of approximately $188,000.

Revaluation of Warrants

Our outstanding warrants were deemed to be derivative instruments that require liability classification and mark-to-market accounting. As such, at the end of each reporting period, the fair values of the warrants were determined by using a Black-Scholes option-pricing model, resulting in the recognition of a loss of $5.6 million for the three months ended June 30, 2013. The exercise of the remaining 865,381 warrants resulted in the recognition of a gain of $55.8 million for the three months ended June 30, 2014. As there are no outstanding warrants at the end of June 30, 2014, we will not need to incur further revaluations.

Other Income (Loss), Net

Other income (loss), 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 net proceeds from our follow-on public offering in April 2014. This investment income was offset by investment interest amortization, investment management fees and franchise and real estate taxes.

Comparison of the Six Months Ended June 30, 2013 and the Six Months Ended June 30, 2014

The following table summarizes our results of operations for each of the six months ended June 30, 2013 and 2014, together with the changes in those items in dollars:

	Six Months Ended June 30,		Dollar Change
	2013	2014	
	(In thousands)		
Licensing revenue	$811	$851	$40
Operating expenses:			
Research and development	9,966	29,212	19,246
General and administrative	5,287	13,606	8,319
Loss from operations	(14,442)	(41,967)	(27,525)
Warrant revaluation income (expense)	(9,255)	(170,832)	(161,577)
Other income, net	10	240	230
Net loss	$(23,687)	$(212,559)	$(188,872)

Licensing Revenue

Licensing revenue was $811,000 and $851,000 million for the six months ended June 30, 2013 and 2014, respectively, resulting from the amortization of the up-front payments a from the collaboration agreement entered into with Sumitomo Dainippon.

Research and Development Expenses

Research and development expenses were $10.0 million and $29.2 million for the six months ended June 30, 2013 and 2014, respectively, representing an increase of $19.2 million. This increase in research and development expense primarily reflects:

- increased direct development expense for activities around our development program for OCA, including manufacturing of drug supply to support clinical trials of OCA and preparation of the NDA and MAA filings for PBC, of approximately $9.3 million;
- increased share-based compensation expense of approximately $5.8 million, primarily due to the re-measurement of previously granted options to consultants;
- an increase in personnel on our development team to manage the increased activities around our development program for OCA, resulting in increased compensation and related benefits expense of approximately $2.5 million;
- increased costs associated with IND-enabling studies for INT-767 of approximately $613,000; and
- increased indirect expenses of approximately $1.0 million, primarily due to increased office related expenses of approximately $500,000 and patent expenses of $300,000.

General and Administrative Expenses

General and administrative expenses were $5.3 million and $13.6 million in the six months ended June 30, 2013 and 2014, respectively. The $8.3 million increase primarily reflects:

- increased share-based compensation expenses of approximately $1.9 million due to an increase in our headcount;
- an increase in personnel to manage the increased activities due to our expanding operations, resulting in increased compensation and related benefits expenses of approximately $2.4 million;
- increased pre-commercialization activities of approximately $2.2 million;
- increased office-related expenses of approximately $492,000 due to the relocation of our corporate headquarters; and
- increased legal, accounting, and securities listing expenses of approximately $288,000 to support our public company operations.

Revaluation of Warrants

Our outstanding warrants are deemed to be derivative instruments that require liability classification and mark-to-market accounting. As such, at the end of each reporting period, the fair values of the warrants were

determined by us using a Black-Scholes option-pricing model, resulting in the recognition of a loss of $9.3 million and $170.8 million for the six months ended June 30, 2013 and 2014, respectively. These fluctuations in value were primarily due to the increase in the price of the common stock underlying the warrants offset by declines in the estimated life of the warrants and the changes in volatility of the shares of common stock underlying the warrants.

Other Income, Net

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investments securities, which increased compared to the prior year period as a result of the proceeds from our follow-up public offering in April 2014, partially offset by investment interest amortization, management fees, for capital base, franchise and real estate taxes.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses since our inception in September 2002 and 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, totaling $435.6 million (net of issuance costs), and the receipt of $17.4 million in up-front payments under our licensing and collaboration agreements with Sumitomo Dainippon and Servier. As of June 30, 2014, we had cash, cash equivalents and investment securities of approximately $299.0 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.

In April 2014, we completed a follow-on public offering of 1,000,000 shares of our common stock, of which 600,000 shares were sold by us and 400,000 shares were sold by certain selling stockholders, at a public offering price of $320.00 per share. After underwriting discounts and commissions and estimated offering expenses, we received net proceeds from the offering of approximately $183.5 million. We did not receive any proceeds from the sale of shares of common stock by the selling stockholders.

Cash Flows

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

	Six Months Ended June 30,	
	2013	2014
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$(11,144)	$(31,728)
Investing activities	(45,825)	(124,686)
Financing activities	63,598	188,012
Net increase in cash and cash equivalents	$6,629	$31,598

Operating Activities. Net cash used in operating activities of $11.1 million during the six months ended June 30, 2013 was primarily a result of our $23.7 million net loss and net changes in operating assets and liabilities of $790,000, partially offset by non-cash items consisting of $9.3 million for warrant liability revaluation, $3.5 million for stock-based compensation, $528,000 for amortization of investment premiums, and $52,000 of depreciation. Net cash used in operating activities of $31.7 million during the six months ended June 30, 2014 was primarily a result of our $212.6 million net loss, partially offset by the add-back of non-cash expenses of $11.2 million for share-based compensation and $170.8 million for warrant liability revaluation, the amortization of investment premium of $1.4 million and net changes in operating assets and liabilities of $2.7 million.

Investing Activities. Net cash used in investing activities for the six months ended June 30, 2014 was $124.7 million as compared to $45.9 million during the same period in 2013. This increase of approximately $78.9 million is attributed to increased purchases of investments of $101.6 million partially offset by the increased sale of our investments of $23.2 million.

Financing Activities. Net cash provided by financing activities for the six months ended June 2014 was $188.0 million compared to $63.6 for the comparable period in 2013. This increase was primarily the result of funds received from the follow-on public offering in April 2014 as well as the exercise of stock options.

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. 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.

Based upon our currently expected level of operating expenditures, we believe that our existing cash, cash equivalents, short-term investments, including the $183.5 million of net proceeds we received from the follow-on public offering in April 2014, and anticipated funding under our Sumitomo Dainippon and Servier collaborations, will enable us to fund our operating expenses and capital expenditure requirements through mid-2016. Although our current plans are still preliminary and subject to change, our current estimate reflects, among other items, the planned initiation of our confirmatory clinical outcomes trial of OCA in PBC and engaging in other planned activities for seeking regulatory approval of OCA in PBC, including several Phase 1 pharmacology clinical trials; the planned initiation of a Phase 2 trial investigating the lipid metabolic effects of OCA in NASH patients; the anticipated initiation of a Phase 2 clinical trial of OCA in PSC; an anticipated increase in pre-commercial and commercial activities for OCA, including activities in preparation of the potential commercial launch of OCA in PBC; the planned initiation of our Phase 3 program in NASH; and pre-clinical studies anticipated to be needed for the submission of an IND for INT-767 and the planned initiation of a Phase 1 clinical trial for INT-767. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

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

- the results of, and the data from, the Phase 2b FLINT trial of OCA in NASH patients and our other clinical trials, and the timing for the receipt of such results and data;
- the willingness of the FDA and EMA to accept our POISE trial, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for review and marketing approval of OCA for PBC;
- the progress, costs, results of and timing of our planned confirmatory clinical outcomes trial of OCA for the treatment of PBC;
- the progress, costs, results of and timing of clinical development of OCA for other indications, including any additional clinical trials that may be needed to continue our development of, and to seek regulatory approval for, OCA in NASH;
- 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 whether we pursue their development independently or with a third-party collaborator;
- the ability of our product candidates to progress through pre-clinical and clinical development successfully and in a timely manner;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities and procuring the materials necessary for the manufacturing of our product candidates;
- market acceptance of our product candidates;
- the costs of acquiring licensing or investing in business, 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 to the intellectual property rights;

- our need and ability to hire additional management, scientific and medical, commercial and other qualified personnel;

- the effect of competing technological and market developments;

- our need to implement additional internal systems, software and infrastructure, including those to assist in our financial and reporting, clinical development and commercialization efforts; and

- the economic and other terms, timing of and success of our existing licensing arrangement and any collaboration, licensing or other arrangement 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 14, 2014.

On May 1, 2014, we entered into a lease agreement with The Irvine Company LLC for our new office in San Diego. The lease will provide us with approximately 47,000 rentable square feet in San Diego for office space. The lease term is anticipated to commence in September 2014 and is anticipated to end in September 2019. We also have an option to further extend the lease for an additional five year term at market rates prevailing at such time.

The rent for the first year will be approximately $874,000 without giving effect to rent abatements and the rent will gradually increase every 12 months during the lease term. During the first six months, we will receive a partial rent abatement from the landlord. The landlord will also provide us with contributions of up to approximately $2.4 million for improvements to the office space.

Pursuant to the terms of the new lease, we have provided the landlord with a letter of credit for $874,000, which will decrease at certain times during the term of the lease.

The Irvine Company LLC, which is also the landlord of our current San Diego office, has agreed to release us from our obligations under the current San Diego lease effective as of the commencement date of the lease for our new San Diego office.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under 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 14, 2014.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or Exchange Act) as of June 30, 2014, have concluded that, based on such evaluation, our disclosure controls and procedures were adequate and effective. In designing and evaluating our disclosure controls and procedures, our management recognized 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 was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control, that occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

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 our January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo. On April 22, 2014, two individuals each moved to consolidate the cases and a lead plaintiff was subsequently appointed by the Court. On June 27, 2014, the lead plaintiff filed an amended complaint on behalf of the putative class as contemplated by the order of the Court. The lead plaintiff seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees.

Additional complaints may be filed against us and our directors and officers related to our disclosures.

We believe that this lawsuit is without merit. 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.

Information regarding risk factors appears in "Forward-Looking Statements" of this Form 10-Q and in "Risk Factors" in Part I – Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013. The risk factors described below update and supersede the corresponding risk factors contained in our Annual Report on Form 10-K.

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 announced the results from the double-blind phase of our Phase 3 POISE trial in March 2014. 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. Based on these results, we currently expect to complete our filling for marketing approval of OCA in PBC in the United States and the European Union during the first half of 2015. 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 January 2014, the NIDDK stopped the double-blind treatment phase of the FLINT trial early following a planned interim analysis showing that OCA had met the primary efficacy endpoint of the trial based on a pre-defined interim efficacy criteria. The NIDDK recently provided us with a draft manuscript describing the results from the FLINT trial to be submitted for publication. This draft manuscript confirmed that OCA met the primary efficacy endpoint of the FLINT trial. However, the NIDDK has not yet provided us with the dataset from the FLINT trial and the manuscript we received is in draft form, is expected to undergo peer review and is subject to further modification prior to publication. The dataset for the FLINT trial or the final manuscript may include additional details regarding OCA that may not be expected or desirable. The Phase 2 trial in NASH currently being conducted in Japan by our collaborator Sumitomo Dainippon involves different doses of OCA being administered to the trial subjects than those utilized in FLINT. Furthermore, we have not made any determinations regarding the design of any future trial in NASH. As a result, the positive efficacy results seen in FLINT may not be replicated in the Japanese trial or any future trial we may conduct in NASH.

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

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

The most common side effects observed in clinical trials of OCA in PBC were pruritus, or itching, fatigue, headaches, nausea, constipation and diarrhea. In our Phase 2 PBC clinical trial of OCA in combination with ursodiol, approximately 8% of the patients enrolled in the 10 mg and 25 mg dose groups withdrew from the trial due to severe pruritus. At the 50 mg dose, approximately 25% of the patients withdrew from the trial due to severe pruritus. In our POISE trial, pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment and was observed in 38% of patients on placebo, 68% of patients in the 10 mg OCA group and 56% of patients in the OCA titration group (5 mgs to 10 mgs). Eight patients discontinued due to pruritus, of whom none were

in the placebo group, seven (10%) patients were in the 10 mg OCA group and one (1%) patient was in the OCA titration group (in a patient who had titrated up to 10 mg). Pruritus also has been observed in other clinical trials of OCA.

Based on information in the draft manuscript for the FLINT trial, pruritus occurred more frequently in the OCA treatment group than in the placebo treatment group (23% vs. 6%, p<0.001) and at a higher grade (predominately moderate pruritus), but resulted in only one patient discontinuation in the OCA treatment group. In the FLINT trial, OCA treatment was associated with changes in serum lipid levels, including increases in total cholesterol and LDL cholesterol and a decrease in HDL cholesterol, that were observed within 12 weeks of initiating treatment, peaked and then decreased in magnitude while on treatment, and reversed further during the 24-week post-treatment period. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments—Serum Lipids" in this 10-Q for more information. As previously disclosed, these changes in cholesterol levels, along with achieving the pre-defined efficacy criteria, played a role in the decision of the FLINT data and safety monitoring board to terminate the treatment phase of FLINT, and the NIDDK has noted the need for further study of these changes. We intend to initiate a Phase 2 trial investigating the lipid metabolic effects of OCA in NASH patients in the first half of 2015. There were two patient deaths in the FLINT trial that were previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013, and neither death was considered related to OCA treatment.

NIDDK has not yet provided us with the dataset from the FLINT trial and the manuscript we received is in draft form, is expected to undergo peer review and is subject to further modification prior to publication. The dataset for the FLINT trial or the final manuscript may include additional details regarding OCA that may not be expected or desirable. We anticipate that the full safety information relating to OCA from the FLINT trial in NASH will be provided to us together with the final results.

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

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

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

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

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

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

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in the United States, Europe and other jurisdictions, including major

multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA or EMA approval or discovering, developing and commercializing drugs for the chronic liver and other diseases that we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Some of the pharmaceutical and biotechnology companies we expect to compete with include Astellas Pharma US, Inc., AstraZeneca, Bristol-Myers Squibb Company, Conatus Pharmaceuticals Inc., Dr. Falk Pharma GmbH, Eli Lilly, Exelixis, Inc., Galectin Therapeutics Inc., Galmed Medical Research Ltd., Genfit SA, Gilead Sciences, Inc., GlaxoSmithKline, Immuron Ltd., Kadmon Corporation LLC, La Jolla Pharmaceutical Company, Lumena Pharmaceuticals, Inc. (now part of Shire PLC), Mochida Pharmaceutical Co., Ltd., NasVax Ltd., NovImmune SA., Novo Nordisk A/S, Phenex Pharmaceuticals AG, Raptor Pharmaceutical Corp., Salix Pharmaceuticals, Inc., Takeda Pharmaceutical Co Ltd, Tioga Pharmaceuticals, Inc. and Tobira Therapeutics. In addition, many universities and private and public research institutes may become active in our target disease areas. Our announcement that the FLINT trial in NASH was stopped early following a planned interim efficacy analysis showing that OCA had met the primary efficacy endpoint of the trial based on a pre-defined interim efficacy criterion has brought more attention to our targeted indications. As a result, we believe that additional companies and organizations may seek to compete with us in the future. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than OCA or any other product candidates that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive.

Off-label uses of other potential treatments may limit the commercial potential of our product candidates, especially given the anticipated pricing for our product candidates. For example, off-label use of fibrate drugs has been reported in PBC, though many fibrates are specifically contraindicated for use in PBC due to potential concerns over acute and long-term safety in this patient population. In NASH, a number of treatments, including vitamin E (an antioxidant), insulin sensitizers (such as metformin), antihyperlipidemic agents (such as gemfibrozil), pentoxifylline and ursodiol, are used off-label. Although none of these treatments have been clearly shown in clinical trials to alter the course of the disease, in a previous study conducted by the NASH Clinical Research Network, similar improvements to those observed with OCA in the FLINT trial in certain histological measures of NASH were reported with vitamin E and pioglitazone. Various other treatments, both approved and unapproved, have been used in the other indications we are targeting.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our and our strategic collaborators' clinical trials and preclinical studies;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to maintain a good relationship with regulatory authorities;
- the timing and scope of regulatory approvals, if any;
- our ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products;
- adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect intellectual property rights related to our products;
- our ability to manufacture and sell commercial quantities of any approved products to the market; and
- acceptance of our product candidates by physicians and other health care providers.

If our competitors market products that are more effective, safer or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

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 six months ended June 30, 2014 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 June 30, 2014, we did not issue or sell any shares on an unregistered basis except as set forth below.

On April 10, 2014, we issued an aggregate of 834,758 shares of common stock upon the cashless exercise by Genextra S.p.A. of all of its warrants to purchase a total of 865,381 shares of common stock. No underwriters were involved in the foregoing sales of securities. The securities described above were issued and sold in reliance on the exemptions from registration provided by Section 4(2) of the Securities Act and/or Rule 506 of Regulation D promulgated under the Securities Act. Genextra S.p.A. represented to us in connection with its purchase that it was acquiring the securities for investment and not for distribution and that it could bear the risks of the investment. Genextra S.p.A. received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from registration.

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.

Use of Proceeds from Registered Securities

On October 10, 2012, we completed our initial public offering of 5,750,000 shares of our common stock at a price of $15.00 per share for aggregate gross proceeds of approximately $86.3 million. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1, which was declared effective on October 10, 2012 (File No. 333-183706), and a registration statement on Form S-1 filed pursuant to Rule 462(b) of the Securities Act (File No. 333-184370).

We received aggregate net proceeds from the offering of approximately $78.7 million, after deducting approximately $6.1 million of underwriting discounts and commissions, and approximately $1.5 million of estimated offering expenses payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to our directors or officers or their associates or to persons owning ten percent or more of our common stock or to any of our affiliates.

We invested the net proceeds from the offering in a variety of capital preservation investments, including money market funds, U.S. Treasury notes and high quality marketable debt instruments of corporate, financial institutions, and government sponsored enterprises. We have broad discretion in the use of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our stock.

As of June 30, 2014, we used the net proceeds from the initial public offering for the following purposes and amounts:

- research and development costs of $15.5 million, including preclinical, regulatory and clinical operations expenses;
- general and administrative costs of $5.3 million, which include personnel and benefit costs as well as costs of operations; and
- pre-commercialization activities of $2.2 million.

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: August 11, 2014 By: /s/ Mark Pruzanski, M.D.
Mark Pruzanski
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2014 By: /s/ Barbara Duncan
Barbara Duncan
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit Index

Exhibit Number	Description of Exhibit
3.1	Amendment to Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on July 22, 2014).
10.1	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2014).#
10.2	Employment Agreement by and between the Registrant and Rachel McMinn, effective as of April 30, 2014 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2014).#
10.3	Form of Restricted Stock Award Grant Notice for Directors under the 2012 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2014).#
10.4	Form of Restricted Stock Award Grant Notice for Employees and Consultants under the 2012 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on May 9, 2014).#
10.5	Lease Agreement between The Irvine Company LLC and the Registrant, dated May 1, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 7, 2014).
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 quarter ended June 30, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at December 31, 2013 and June 30, 2014 (unaudited), (ii) Condensed Consolidated Statements of Operations for the three and six month periods ended June 30, 2013 and 2014 (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three month and six month periods ended June 30, 2013 and 2014 (unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the three and six month periods ended June 30, 2013 and 2014 (unaudited) and (v) Notes to Condensed Consolidated Financial Statements (unaudited).+

Management or director compensation plan or policy.

+ Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability under these sections.