INTERCEPT PHARMACEUTICALS INC
Form 10-Q
November 06, 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 September 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 Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
450 West 15th Street, Suite 505 New York, NY	**10011**
(Address of Principal Executive Offices)	**(Zip Code)**

(646) 747-1000

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer ¨		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 October 31, 2014, there were 21,359,677 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 in Europe;
- 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 and our follow-on public offerings of common stock;
- 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 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, and in our subsequent periodic and current reports filed with the Securities and Exchange Commission, including this Quarterly Report on Form 10-Q. Those risk factors, together with any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

PART I

Item 1. FINANCIAL STATEMENTS

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

	December 31, 2013 (Audited)	September 30, 2014 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$13,363,185	$18,059,045
Investment securities, available-for-sale	131,468,797	254,747,198
Prepaid expenses and other current assets	2,732,556	6,282,505
Total current assets	147,564,538	279,088,748
Fixed assets, net	1,672,295	5,131,360
Security deposits	1,081,747	1,800,683
Total assets	$150,318,580	$286,020,791
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$7,259,805	$14,714,346
Short-term portion of deferred revenue	1,621,622	1,781,620
Total current liabilities	8,881,427	16,495,966
Long-term liabilities:		
Long-term portion of deferred revenue	8,918,916	8,462,705
Long-term portion of warrant liability	50,112,137	-
Total liabilities	67,912,480	24,958,671
Stockholders' equity:		
Common stock. 35,000,000 shares authorized; 19,389,610 and 21,323,549 shares issued and outstanding as of December 31, 2013 and September 30, 2014, respectively; par value $0.001 per share	19,390	21,324
Additional paid-in capital	268,302,617	695,621,511
Accumulated other comprehensive income (loss), net	59,853	(203,078)
Accumulated deficit	(185,975,760)	(434,377,637)
Total stockholders' equity	82,406,100	261,062,120
Total liabilities and stockholders' equity	$150,318,580	$286,020,791

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 September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
Licensing revenue	$405,407	$445,405	$1,216,219	$1,296,213
Costs and expenses:				
Research and development	8,392,628	27,380,958	18,358,155	56,592,841
General and administrative	3,115,095	9,135,968	8,402,454	22,741,998
Total costs and expenses	11,507,723	36,516,926	26,760,609	79,334,839
Other income (expense):				
Revaluation of warrants	(20,756,086)	-	(30,010,672)	(170,831,872)
Other income, net	121,329	228,247	130,924	468,621
	(20,634,757)	228,247	(29,879,748)	(170,363,251)
Net loss	$(31,737,073)	$(35,843,274)	$(55,424,138)	$(248,401,877)
Net loss per share:				
Basic and diluted	$(1.65)	$(1.69)	$(3.15)	$(12.07)
Weighted average shares outstanding:				
Basic and diluted	19,198,923	21,260,303	17,585,531	20,583,146

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
Net loss	$(31,737,073)	$(35,843,274)	$(55,424,138)	$(248,401,877)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities:				
Unrealized holding gains (losses) arising during the period	140,397	(189,542)	52,557	(286,642)
Reclassification for recognized gains on marketable investment securities during the period	-	19,601	-	23,711
Net unrealized gains (losses) on marketable investment securities	$140,397	$(169,941)	$52,557	$(262,931)
Comprehensive loss	$(31,596,676)	$(36,013,215)	$(55,371,581)	$(248,664,808)

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2013	2014
Cash flows from operating activities:		
Net loss	$ (55,424,138)	$ (248,401,877)
Adjustments to reconcile net loss to net cash used in operating activities:		
Revaluation of warrants	30,010,672	170,831,872
Share-based compensation	6,478,346	16,463,619
Depreciation	79,370	210,196
Loss on the disposal of property and equipment	-	20,913
Amortization of investment premium	1,076,157	2,390,707
Changes in:		
Prepaid expenses, other current assets and security deposits	80,900	(4,268,885)
Accounts payable, accrued expenses and other current liabilities	1,333,808	7,454,541
Deferred revenue	(1,216,219)	(296,213)
Net cash used in operating activities	(17,581,104)	(55,595,127)
Cash flows from investing activities:		
Purchases of investment securities	(86,231,665)	(195,976,777)
Sales of investment securities	26,436,682	70,044,738
Purchases of equipment, improvements, and furniture and fixtures	(121,205)	(3,690,174)
Net cash used in investing activities	(59,916,188)	(129,622,213)
Cash flows from financing activities:		
Proceeds from issuance of stock offerings, net of issuance costs	61,169,317	183,475,222
Proceeds from exercise of options	4,300,250	6,437,978
Proceeds from exercise of warrants	8,101	-
Net cash provided by financing activities	65,477,668	189,913,200
Net increase in cash and cash equivalents	(12,019,624)	4,695,860
Cash and cash equivalents – beginning of period	45,511,641	13,363,185
Cash and cash equivalents – end of period	$ 33,492,017	$ 18,059,045
Supplemental disclosures of noncash activities:		
Issuance of common stock for cashless warrant exchange	$ 8,445,833	$ 220,944,009

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1.*Overview of Business*

Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company"), is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat 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 and a wholly-owned subsidiary in the United Kingdom. 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 nine months ended September 30, 2013 and September 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. During the second quarter of 2014, the Company adopted 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.

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 September 30, 2013 and 2014, the Company recorded revenue of approximately $405,000 and $445,000, respectively, and during the nine months ended September 30, 2013 and 2014, the Company recorded revenue of approximately $1.2 million and $1.3 million, respectively, in “Licensing Revenue” in its Condensed Consolidated Statement of

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INTERCEPT PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

Operations for the Company's efforts under the agreement. The Company has not achieved any of the milestones relating to the agreement as of September 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 September 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 September 30, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$18,059	$ -	$ -	$18,059

Investment securities:				
Commercial paper	12,993	1	(1)	12,993
Corporate debt securities	216,135	74	(240)	215,969
U.S. government and agency securities	25,817	2	(34)	25,785
Total investments	254,945	77	(275)	254,747
Total cash, cash equivalents and investments	$273,004	$ 77	$ (275)	$272,806

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:

INTERCEPT PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

	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 September 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	$39,229	$ (15)	$ 103,690	$ (225)	$142,919	$ (240)
Commercial paper	2,996	(1)	-	-	2,996	(1)
U.S. government and agency securities	-	-	14,713	(34)	14,713	(34)
Total	$42,225	$ (16)	$ 118,403	$ (259)	$160,628	$ (275)

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 September 30, 2014, the Company had available net operating loss carryforwards to reduce future taxable income of approximately $108.2 million and $179.2 million, respectively, for tax reporting purposes. These carryforwards expire between 2024 and 2033. 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 $91.2 million at December 31, 2013 and September 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.

INTERCEPT PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

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, were 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, 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 and as such no further revaluations are required.

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:

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- 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 equivalents are classified within Level 1 of the fair value hierarchy because they are valued using 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 was 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:

INTERCEPT PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

	Total	Fair Value Measurements Using 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)
September 30, 2014				
Assets:				
Money market funds	$16,361	$16,361	$ -	$ -
Available for sale securities:				
Commercial paper	12,993	-	12,993	-
Corporate debt securities	215,969	-	215,969	-
U.S. government and agency securities	25,785	-	25,785	-
Total financial assets	$271,108	$16,361	$254,747	$ -

INTERCEPT PHARMACEUTICALS, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

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 nine month period ended September 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 September 30, 2014	$ -

The Company determined the fair value of its warrant liability under 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	**September 30, 2014**
	(In thousands)	
Due in one year or less	$56,044	$ 123,265
Due after 1 year through 2 years	75,425	131,482
Total investments in debt securities	$131,469	$ 254,747

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 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 offering expenses, the Company received

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(Unaudited)

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 September 30, 2014, the Company was authorized to issue 35,000,000 shares of common stock, $0.001 par value per share, and 5,000,000 shares of preferred stock, $0.001 par value per share.

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 September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
	(In thousands)			
General and administrative	$1,181	$2,357	$3,107	$6,178
Research and development	1,800	2,877	3,371	10,286

Total share-based compensation	$2,981	$5,234	$6,478	$16,464

The following table summarizes stock option activity during the nine months ended September 30, 2014:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2013	1,524,837	$ 21.32
Granted	231,386	$ 255.97
Exercised	(407,399)	$ 16.04
Forfeited	(5,991)	$ 90.16
Outstanding, September 30, 2014	1,342,833	$ 63.05
Exercisable, September 30, 2014	664,615	$ 15.17

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 September 30, 2014, the achievement of the milestones was not deemed to be probable and no share-based compensation expense was recognized for these options.

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The following table summarizes the aggregate activities in relation to Restricted Stock Units (RSU) and Restricted Stock Awards (RSA):

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding, December 31, 2013	121,069	$ 25.30
Granted	42,999	$ 255.26
Exercised	(50,158)	$ 34.33
Forfeited	(1,743)	$ 221.25
Outstanding, September 30, 2014	112,167	$ 117.53

9. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
	(In thousands, except share and per share amounts)			
Historical net loss per share				
Numerator:				
Net loss attributable to common stockholders	$(31,737)	$(35,843)	$(55,424)	$(248,402)
Denominator:				
Weighted average shares used in calculating net loss per share - basic and diluted	19,198,923	21,260,303	17,585,531	20,583,146
Net loss per share:				
Basic and diluted	$(1.65)	$(1.69)	$(3.15)	$(12.07)

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

	September 30,	
	2013	2014
	(In thousands)	
Options	1,535	1,343
Warrants to purchase common stock	878	-
Restricted stock units	135	71
Total	2,548	1,414

10. Litigation

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

The lawsuits allege that the Company made material misrepresentations and/or omissions of material fact in its public disclosures during the period from January 9, 2014 to January 10, 2014, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to the Company's January 9, 2014 announcement that the FLINT trial had been stopped early based on a pre-defined interim efficacy analysis. Specifically, the lawsuits claim that the January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo. On April 22, 2014, two individuals each moved to consolidate the cases and a lead plaintiff was subsequently appointed by the Court. On June 27, 2014, the lead plaintiff filed an amended complaint on behalf of the putative class as contemplated by the order of the Court. On August 14, 2014, the defendants filed a motion to dismiss the complaint, which has been opposed by the lead plaintiff. 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). During the second quarter of 2014, the Company adopted this 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 could be achieved after the requisite service period 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 evaluated this amendment and determined there was no impact on the current financial statements.

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In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* The FASB issued this update to provide guidance regarding when and how management should disclose conditions and events that raise substantial doubt about an organizations ability to continue as a going concern. The update clarifies that management is responsible for evaluating and disclosing those conditions and issues. The amendments in this update are effective for annual periods ending after December 15, 2016 and for annual periods and interim periods thereafter. 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, including this Quarterly Report on Form 10-Q, 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. Our most advanced development program for OCA is 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. Following discussions with the FDA, we have finalized the protocol for our clinical outcomes confirmatory trial for OCA in PBC, and expect to initiate the trial around year end 2014. 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.

OCA was also 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. FLINT was completed in late July 2014 and an initial draft manuscript summarizing the FLINT data was sent to us by NIDDK in early August 2014. We disclosed top line

FLINT data set forth in the draft manuscript in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2014. We are in discussions with the NIDDK with respect to the transfer to us of the detailed FLINT datasets. We plan to initiate our Phase 3 clinical program for NASH in the first half of 2015 subject to our review of the detailed FLINT data and the successful completion of regulatory discussions.

In addition to PBC and NASH, we plan to continue our research on OCA in other patient populations suffering from liver and non-liver related diseases, as we believe that FXR has broad therapeutic potential. Near term, we anticipate initiating a randomized Phase 2 trial for OCA in primary sclerosing cholangitis, or PSC, around year end 2014. We are currently evaluating our future development strategy for OCA in other indications and for our pre-clinical candidates. As part of our pipeline development, we plan to complete IND-enabling studies for INT-767 and, initiate a Phase 1 trial in 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 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 September 30, 2013 and 2014 was approximately $31.7 million and $35.8 million, respectively. Included in the net loss for the three months ended September 30, 2013 and 2014 is $20.8 million and $0 for the non-cash charge for the warrant liability revaluation and $3.0 million and $5.2 million respectively for non-cash share based compensation. Our net loss for the nine months ended September 30, 2013 and 2014 was $55.4 million and $248.4 million, respectively. Included in the net loss for the nine months ended September 30, 2013 and 2014 is $30.0 million and $170.8 million, respectively, for the non-cash charge for the warrant liability revaluation and $6.5 million and $16.5 million, respectively, for non-cash share based compensation. 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 adjustment of our liability-classified warrants.

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

- complete the development of our lead product candidate, OCA, for the treatment of PBC, 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;
- expand our operations in the United States and Europe;
- 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 and a wholly-owned subsidiary in the United Kingdom.

Financial Overview

Revenue

To date, we have not generated any revenue from the sale of products. All of our revenue has been derived from our collaborative agreements for the development and commercialization of certain of our product candidates. 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 nine months ended September 30, 2013 and 2014, we recognized approximately $1.2 million and $1.3 million 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 up-front 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 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, PSC and other indications and continue to advance the development of our other product candidates such as INT-767, subject to the availability of additional funding. In respect to our OCA program, we currently plan to focus our efforts and resources on PBC, NASH and PSC, and do not intend to direct a significant amount of resources to other indications.

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 and commercial 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.

	Nine Months Ended September 30,	
	2013	2014
	(In thousands)	
Direct research and development expense by program:		
OCA	$ 10,522	$ 34,535
INT-767	411	1,293
INT-777	49	–
Total direct research and development expense	10,982	35,828
Personnel costs (1)	6,671	18,114
Indirect research and development expense	705	2,651
Total research and development expense	$ 18,358	$ 56,593

(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 $3.4 million and $10.3 million for the nine months ended September 30, 2013 and 2014, respectively. During the nine months ended September 30, 2014, we added 34 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 current 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 during 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 have finalized the protocol for our clinical outcomes confirmatory trial for OCA in PBC and expect to initiate this trial around year end 2014. We expect that the clinical outcomes trial will be completed on a post-marketing basis.
- We have conducted 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 and 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 as part of our strategy to secure more than one approved supplier of OCA in the future. We 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, particularly NASH and PSC. 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 in the first half of 2015. We intend to initiate a Phase 2 trial investigating the lipid metabolic effects of OCA in NASH patients in 2015. For PSC, we intend to initiate a Phase 2 clinical trial around year end 2014. As a result, we expect that our expenditures in connection with our NASH and PSC programs will increase significantly in future periods.

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, plan to initiate a Phase 1 trial of INT-767 in healthy volunteers in 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 and other expenses of operating as a public company.

Our general and administrative expenses have increased and will continue to increase as we operate as a public company and due to the potential commercialization of our product candidates. We further plan on expanding our operations both in the United States and Europe, which will increase our general and administrative expenses. We believe that these activities will likely result in increased costs related to the addition of facilities, the hiring of significant 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 with expanding operations. In 2014, we have also implemented a number of software, systems and other infrastructural changes in relation to our operations as a public company. During the nine months ended September 30, 2014, we added 28 corporate and commercial personnel.

Other Income, Net

Other income, 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 September 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 provided for a reduction in the warrant exercise price upon subsequent issuances of additional shares of common stock for consideration per share less than the applicable per share warrant exercise price. The warrants containing this provision, 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 was recorded as a component of other income and expense.

Results of Operations

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

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

	Three Months Ended September 30,		Dollar Change
	2013	2014	
	(In thousands)		
Licensing revenue	$ 405	$ 445	$ 40
Operating expenses:			
Research and development	8,392	27,381	18,989
General and administrative	3,115	9,136	6,021
Loss from operations	(11,102)	(36,072)	(24,970)
Warrant revaluation (expense)	(20,756)	–	20,756
Other income, net	121	228	107
Net loss	$ (31,737)	$ (35,844)	$ (4,107)

Licensing Revenue

Licensing revenue was $405,000 and $445,000 for the three months ended September 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 $8.4 million and $27.4 million for the three months ended September 30, 2013 and 2014, respectively, representing an increase of $19.0 million. This increase in research and development expense primarily reflects:

- increased direct development expense for activities around our development program for OCA of approximately $14.7 million primarily due to:
  - increased clinical operations expenses of approximately $10.4 million, primarily due to;
    - increased expenses of $9.2 million relating to Phase 1 clinical trials;
    - increased expenses of $662,000 relating to our Phase 3 POISE trial and LTSE phase; and
    - increased expenses of $493,000 relating to our Phase 2 PBC lipoprotein study;
  - increased product development costs related to our clinical and commercial supplies of approximately $2.6 million; and
  - an increase in other research and development costs of approximately $1.6 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 $2.0 million;
- increased non-cash share-based compensation expense of approximately $1.1 million, primarily related to increased headcount; and
- increased indirect costs of approximately $1.0 million due to increased office related expenses of approximately $707,000, increased patent costs of $169,000 and increased travel-related expenses of $164,000.

General and Administrative Expenses

General and administrative expenses were $3.1 million and $9.1 million in the three months ended September 30, 2013 and 2014, respectively. The $6.0 million increase primarily reflects:

- an increase in personnel to manage increased activities due to our expanding operations, resulting in increased compensation and related benefits expense of approximately $1.7 million, of which approximately $900,000 was related to corporate operations and $800,000 was related to commercial operations;
- an increase in non-cash share-based compensation expense of approximately $1.2 million due to increased headcount;
- increased pre-commercial activities of approximately $1.3 million;
- increased legal expenses of approximately $933,000;
- increased other general corporate expenses of approximately $702,000, primarily due to market research costs, other office related expenses, corporate travel costs and other office related technologies; and
- increased rent and utilities of approximately $194,000.

Revaluation of Warrants

Our previously outstanding warrants were deemed to be derivative instruments that required 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 $20.8 million for the three months ended September 30, 2013. As there were no outstanding warrants at the end of September 30, 2014, we were not required to revalue the warrants as of such date.

Other Income, Net

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which increased compared to the prior year period as a result of the net proceeds from our follow-on public offering in April 2014. This investment income was offset by investment interest amortization and investment management fees.

Comparison of the Nine Months Ended September 30, 2013 and the Nine Months Ended September 30, 2014

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

	Nine Months Ended September 30,		Dollar Change
	2013	2014	
	(In thousands)		
Licensing revenue	$1,216	$1,296	$ 80
Operating expenses:			
Research and development	18,358	56,593	38,235
General and administrative	8,402	22,742	14,340
Loss from operations	(25,544)	(78,039)	(52,495)
Warrant revaluation (expense)	(30,011)	(170,832)	(140,821)
Other income, net	131	469	338
Net loss	$(55,424)	$(248,402)	$ (192,978)

Licensing Revenue

Licensing revenue was $1.2 million and $1.3 million for the nine months ended September 30, 2013 and 2014, respectively, resulting from the amortization of the up-front payments from the collaboration agreement entered into with Sumitomo Dainippon.

Research and Development Expenses

Research and development expenses were $18.4 million and $56.6 million for the nine months ended September 30, 2013 and 2014, respectively, representing an increase of $38.2 million. This increase in research and development expense primarily reflects:

- increased direct development expense for activities around our development program for OCA of approximately $24.0 million, primarily due to:
  - increased clinical operations expenses of approximately $16.9 million, primarily due to:
    - increased expenses of $14.5 million relating to Phase 1 clinical trials;
  - increased expenses of $1.4 million relating to our Phase 2 PBC lipoprotein study; and

- increased expenses of $1.0 million relating to our Phase 3 POISE trial and LTSE phase;
- increased product development costs related to our clinical and commercial supplies of approximately $4.3 million; and
- an increase in other research and development costs of approximately of $2.8 million;
- increased share-based compensation expense of approximately $6.9 million, primarily due to the re-measurement of previously granted options to consultants and increased headcount;
- 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 $4.5 million;
- increased indirect expenses of approximately $1.9 million, due to:
  - office related expenses of approximately $867,000;
  - patent expenses of approximately $465,000;
  - travel-related expenses of approximately $346,000; and
  - technology related expenses of approximately $267,000; and
- increased costs associated with IND-enabling studies for INT-767 of approximately $882,000.

General and Administrative Expenses

General and administrative expenses were $8.4 million and $22.7 million in the nine months ended September 30, 2013 and 2014, respectively. The $14.3 million increase primarily reflects:

- an increase in personnel to manage the increased activities due to our expanding operations, resulting in increased compensation and related benefits expenses of approximately $4.0 million;
- increased pre-commercialization activities of approximately $3.9 million;
- increased non-cash share-based compensation expenses of approximately $3.1 million due to an increase in our headcount;

- increased legal and related expenses of approximately $1.5 million;
- increased general corporate expenses of approximately $1.3 million, primarily due to:
  - $465,000 in office related technology;
  - $419,000 in other office related expenses;
  - $234,000 in competitor market research costs; and
  - $208,000 in corporate travel costs; and
- increased rent and utilities of approximately $562,000.

Revaluation of Warrants

Our previously outstanding warrants were deemed to be derivative instruments that required 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 $30.0 million and $170.8 million for the nine months ended September 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, investment management fees, and 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 September 30, 2014, we had cash, cash equivalents and investment securities of approximately $273.0 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 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:

	Nine Months Ended September 30,	
	2013	2014
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (17,581)	$ (55,595)
Investing activities	(59,916)	(129,622)
Financing activities	65,478	189,913
Net (decrease) increase in cash and cash equivalents	$ (12,019)	$ 4,696

Operating Activities. Net cash used in operating activities of $17.6 million during the nine months ended September 30, 2013 was primarily a result of our $55.4 million net loss and net changes in operating assets and liabilities of $198,000, partially offset by non-cash items consisting of $30.0 million for warrant liability revaluation, $6.5 million for stock-based compensation, $1.1 million for amortization of investment premiums and $79,000 of depreciation. Net cash used in operating activities of $55.6 million during the nine months ended September 30, 2014 was primarily a result of our $248.4 million net loss, partially offset by the add-back of non-cash items of $16.5 million for share-based compensation, $170.8 million for warrant liability revaluation, $2.4 million for the amortization of investment premium and $2.9 million due to net changes in operating assets and liabilities.

Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2014 was $129.6 million as compared to $59.9 million during the same period in 2013. This increase of approximately $69.7 million is attributed to a net increase in our net purchases of investments of $66.1 million and increased fixed asset purchases for our expanded facilities of $3.6 million.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2014 was $189.9 million compared to $65.5 million 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 and further plan on expanding our operations both in the United States and Europe. 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, 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; 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, our clinical trials, and the timing for the receipt of such results and data, including the timing of the transfer to us of the detailed FLINT datasets;
- 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 both in the United States and in Europe;

- 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;

- our plan to expand our operations into Europe and the manner in which we implement our expansion plan; 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 commenced 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.

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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 nine 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.

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 September 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.

In 2013, the Committee of Sponsoring Organizations or COSO, updated its 1992 *Internal Control – Integrated Framework* which is relied on to achieve compliance with the Sarbanes–Oxley Act. The new framework requires 17 principles of internal control to be present and functioning before an entity can assess that it has adequate control over financial reporting. We delayed the implementation of the 2013 framework until 2015, primarily because of the implementation of a new enterprise resource planning system in the second half of 2014. We feel the additional time to implement the 2013 framework will provide us the time to evaluate and address the risks to our organization in view of our changing size and global presence.

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. On August 14, 2014, the defendants filed a motion to dismiss the complaint, which has been opposed by the lead plaintiff. 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.

Other than as discussed below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2013 and any updates to those risk factors contained in our

subsequent periodic and current reports filed with the Securities and Exchange Commission. The risk factors described below update and supersede the corresponding risk factors contained in our Annual Report on Form 10-K. For a further discussion of our Risk Factors, refer to the "Risk Factors" discussion contained in such filings.

Risks Related to Regulatory Review and Approval of Our Product Candidates

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

We are initially developing OCA for the treatment of patient populations with liver and intestinal diseases, with a current principal focus on PBC, NASH and PSC and our business currently depends entirely on the successful development and commercialization of OCA. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of OCA, particularly for the treatment of PBC, NASH and PSC, and our other product candidates.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States, the EMA in Europe and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States or Europe until we receive approval of an NDA from the FDA or an MAA from the EMA, respectively. We have not submitted any marketing applications for any of our product candidates.

NDAs and MAAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA or an MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions, such as the EMA, have their own procedures for approval of product candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays

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

We 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 have completed a randomized, placebo-controlled Phase 3 trial of OCA in PBC patients, which we refer to as the POISE trial, and two randomized, placebo-controlled Phase 2 trials of OCA in PBC patients, one with OCA in combination with ursodiol and one with OCA as monotherapy. We must complete other preclinical and clinical studies, such as a biocomparability trial comparing the pharmacokinetics of our proposed commercial product to the products utilized in our POISE trial and our Phase 2 trials for OCA in PBC, 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, additional clinical pharmacology trials, including, but not limited to, drug interactions, the effects of food and drug-disease interaction studies, and two-year, two-species carcinogenicity studies, some of which are ongoing. We are also conducting other trials and studies to support our planned NDA and MAA filings, including a trial to evaluate the potential effects and clinical significance of OCA on the lipid profile of patients with PBC. In addition, before we complete our NDA submission with the FDA for OCA for the treatment of patients with PBC, it is likely that we also must have received for inclusion in the filing the safety and tolerability data from the FLINT trial, which was sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases, a division of the National Institutes of Health. Furthermore, we will need to complete a number of clinical trials and other studies for the continued development of OCA in indications other than PBC. For example, we are currently planning for at least one additional Phase 3 clinical trial in NASH, a Phase 2 trial investigating the lipid metabolic effects of OCA in NASH patients and a Phase 2 trial of OCA in pediatric NASH patients prior to seeking regulatory approval of OCA in NASH. In each of these cases, our ability to obtain the approvals necessary to commercialize our product candidates will depend on our ability to conduct and complete these additional trials as well as assemble various other data to complete our regulatory filings for OCA in PBC. There can be no assurance that we will be able to complete these filings on a timely basis or that, even if the filings are completed, that the FDA or EMA will provide marketing approval for OCA in PBC. We cannot predict whether our trials and studies as to NASH or any other indication or patient population will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or require us to conduct additional studies or trials.

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

We are developing product candidates for the treatment of rare diseases or diseases for which there are no or limited therapies and for some of which there is little clinical experience, and our development approach involves

new endpoints and methodologies. As a result, there is increased risk that we will not be able to gain agreement with regulatory authorities regarding an acceptable development plan, the outcome of our clinical trials will not be favorable or that, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval.

Currently, there are no approved therapies for NASH or PSC. In PBC, although ursodiol is the standard of care, studies have shown that up to 50% of PBC patients fail to respond adequately to treatment, meaning that they continue to be at significant risk of progressing to liver failure even with treatment. As a result, the design and conduct of clinical trials for these diseases and other indications we may pursue will be subject to increased risk.

For full approval of an NDA, the FDA requires a demonstration of efficacy based on a clinical benefit endpoint. Typically, the FDA requires two pivotal clinical trials to approve an NDA. However, for OCA as a treatment for PBC, we currently plan to request accelerated approval from the FDA based on the Phase 3 POISE trial, the primary endpoint of which is a surrogate endpoint that we believe is reasonably likely to predict clinical benefit, therefore meeting the FDA's requirements for consideration under its accelerated approval regulation. However, the FDA has not yet provided any assurance that it will accept our approach, and it is unlikely we will receive definitive written guidance from the FDA prior to submitting an NDA as to the acceptability of the POISE trial surrogate endpoint to support an approval of OCA for the treatment of PBC. We anticipate that similar risks will apply to other indications, such as NASH, for which we intend to seek marketing approval for our product candidates under accelerated approval regulations.

In order to build additional consensus regarding the clinical utility of the surrogate endpoint for OCA as a treatment for PBC, we are sponsoring an independent study pooling and analyzing long-term PBC patient data from a number of leading PBC academic centers, which are referred to as the Global PBC Study Group. Furthermore, an academic consortium in the United Kingdom has published the results of another large observational study in PBC patients in the United Kingdom. Although we believe the results of both studies are supportive of the clinical utility of our surrogate endpoint for the use of OCA in PBC, the supporting data may still not be accepted by the FDA in its consideration of the adequacy of our surrogate endpoint under an NDA for OCA for the treatment of PBC. In addition to the risk around the acceptability of the surrogate biochemical endpoint to support accelerated approval, there are quality assurance risks around the data supporting assessment of the biochemical endpoint. It is possible that key parameters such as the validation of the assay and consistency across laboratories will not be acceptable to FDA and could delay or jeopardize approval of the NDA.

The FDA has also informed us that, even if it provides us an accelerated approval for OCA, we will be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of OCA in PBC by demonstrating the correlation of biochemical therapeutic response in patients taking OCA with a significant reduction in adverse clinical outcomes over time. We believe that this clinical outcomes confirmatory trial will need to be underway at the time we submit an NDA. Following discussions with the FDA, we have finalized the protocol for our clinical outcomes confirmatory trial for OCA in PBC, and expect to initiate the trial around year end 2014. There can be no assurance that our clinical outcomes confirmatory trial will confirm that the surrogate endpoints used for accelerated approval will eventually show an adequate correlation with clinical outcomes. If the clinical outcomes confirmatory trial fails to show such adequate correlation, we may not be able to maintain our previously granted marketing approval for OCA in PBC.

Likewise, it is possible that any marketing authorization we receive from the EMA for OCA for the treatment of PBC could be conditional. Our ability to obtain and maintain conditional marketing authorization in the European Union, will be limited to specific circumstances and subject to several conditions and obligations, if obtained at all, including the completion of a clinical outcomes trial to confirm the clinical benefit of OCA in PBC. Conditional marketing authorizations based on incomplete clinical data may be granted for a limited number of listed medicinal products for human use, including products designated as orphan medicinal products under European Union law, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, including with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data, may be specified in the conditional marketing authorization. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions.

In NASH, we currently anticipate that we will need to conduct at least one Phase 3 clinical trial prior to applying for marketing approval for OCA in NASH. We expect this Phase 3 trial would incorporate an interim surrogate endpoint that may serve as the basis for filing for accelerated approval in the United States and approval in Europe. Accelerated approval in the United States and conditional approval in the European Union for OCA in NASH are subject to similar risks as discussed above in relation to OCA for PBC. The primary endpoint in the Phase 2b FLINT trial of OCA in NASH patients was based on liver biopsy and was defined as an improvement of two or more points in the NAFLD activity score (a system of scoring the histopathological features in the liver) with no worsening of liver fibrosis. Currently, other biopharmaceutical companies are enrolling or have initiated trials in certain subpopulations of NASH patients based on different endpoints from the one used in the FLINT trial. Although the FDA acknowledged the possibility of granting accelerated approval for NASH therapies using surrogate endpoints such as the hepatic venous pressure gradient, or HVPG, or histology at a workshop held in September 2013, the FDA did not provide any formal regulatory guidance on approvable endpoints and may not accept a surrogate endpoint for OCA for the treatment of NASH.

Because the FDA normally requires two pivotal clinical trials to approve an NDA, even if we achieve favorable results in a single Phase 3 clinical trial, the FDA may not accept this one trial as an adequate basis for approval and require that we conduct and complete a second Phase 3 clinical trial before considering an NDA for any of the

indications for which we may seek marketing approval for our product candidates. We intend to file an NDA for OCA for the treatment of PBC based on the results of three clinical trials — the POISE trial and two Phase 2 trials. It is possible that our NDA submission for regulatory approval will not be accepted by the FDA for review or, even if it is accepted for review, that there may be delays in the FDA's review process and that the FDA may determine that our NDA does not merit the approval of OCA for the treatment of PBC, in particular because we have only conducted a single Phase 3 clinical trial of OCA for the treatment of PBC, in which case the FDA may require that we conduct and/or complete additional clinical trials and preclinical studies before it will reconsider our application for approval. A similar risk applies if we seek marketing approval of OCA for NASH based on a single Phase 3 pivotal trial**.** Our regulatory pathway for OCA for the treatment of NASH will depend upon our review and analysis of the final dataset for the FLINT trial and the discussions that we plan to hold with the FDA and EMA. As a result, we may face difficulty in designing an acceptable registration strategy around the design of any follow-on trials to the FLINT trial. In addition, it is likely that the primary and possibly other endpoints in future clinical trials of OCA for NASH will be different from those of the FLINT trial. The use of different endpoints, or other trial design changes, would increase the risk that the results of these future trials would differ from the FLINT results.

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

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

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We completed the treatment of patients in the double-blind phase of our POISE trial in December 2013. We plan to initiate our clinical outcomes confirmatory trial in PBC around year end 2014. We also intend to initiate a Phase 2 trial in PSC around year end 2014. We anticipate that we will need to conduct at least one Phase 3 clinical trial prior to applying for marketing approval for NASH, and we plan to initiate our Phase 3 program for NASH in the first half of 2015 subject to our review of the detailed FLINT data and the

completion of successful regulatory discussions. The results from these trials may not be available when we expect or we may be required to conduct additional clinical trials or preclinical studies not currently planned to receive approval for OCA as a treatment for the related indication, in which case we would require additional funding. In addition, our clinical programs are subject to a number of variables and contingencies, such as the results of other trials or regulatory interactions that may result in a change in timing. As such, we do not know whether any future trials or studies of our other product candidates, including our clinical outcomes trial of OCA, will begin on time or will be completed on schedule, if at all.

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

- inability to obtain sufficient funds required for a clinical trial or lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our product candidates;
- the delay in receiving results from or the failure to achieve the necessary results in other clinical trials;
- inability to obtain approval from institutional review boards, or IRBs, to conduct a clinical trial at their respective sites;
- severe or unexpected drug-related adverse effects experienced by patients or any determination that a clinical trial presents unacceptable health risks;
- a breach of the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates, including Sumitomo Dainippon and Servier or investigators leading clinical trials on our product candidates;
- inability to timely manufacture sufficient quantities of the product candidate required for a clinical trial;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our trial, the risks of procedures that may be required as part of the trial, such as a liver biopsy, and competition from other clinical trial programs for the same indications as our product candidates; and
- inability to retain enrolled patients after a clinical trial is underway.

For example, in the past, we experienced delays in our Phase 2 clinical trial of OCA given as a monotherapy to patients with PBC because we were unable to find and enroll a sufficient number of trial patients who met the specific enrollment criteria in accordance with our anticipated trial schedule. The anticipated initiation of our Phase 3 program for OCA in NASH in the first half of 2015 is dependent upon our receiving the detailed FLINT data and successfully completing regulatory discussions.

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

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

Risks Related to Our Business and Strategy

We have been significantly expanding our operations and the size of our company and will need to continue our expansion. We may experience difficulties in managing our significant growth.

From December 31, 2013 to October 31, 2014, our employee base has grown from 40 to 122 employees. Of the 122 employees as of October 31, 2014, 83 employees are in our development group, 17 employees are in our commercial group and 22 employees are in our corporate group. As we advance our programs for OCA in PBC, NASH and PSC and seek regulatory approval in the United States and elsewhere, increase the number of ongoing product development programs and advance our product candidates through preclinical studies and clinical trials, we will need to increase our product development, scientific and administrative headcount to manage these programs. We will also need to grow our commercial capabilities, which will require us to hire additional personnel, both for our ongoing pre-commercial activities and for the launch and ongoing marketing and sale of any product candidate for which we obtain marketing approval. In addition, to meet our obligations as a public company and to support the anticipated growth in the other functions at our company, we will need to increase our general and administrative capabilities. Furthermore, we have also recently formed a wholly-owned subsidiary in the United Kingdom which we anticipate will serve as our headquarters for our operations in Europe and anticipate building out our European operations. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the expertise and experience we will require in the United States and Europe;

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- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites across the world, and advance our other development efforts;
- develop and expand our marketing and sales infrastructure; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

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 nine months ended September 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 September 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 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 September 30, 2014, we used the net proceeds from the initial public offering for the following purposes and amounts:

- research and development costs of $43.8 million, including preclinical, regulatory and clinical operations expenses;
- general and administrative costs of $13.1 million, which include personnel and benefit costs as well as costs of operations; and
- pre-commercialization activities of $6.2 million.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

In September 2014, Paolo Fundaro, a member of our board of directors, entered into a pre-arranged stock trading plan pursuant to Rule 10b5-1 of the Exchange Act to sell up to 4,500 shares of common stock. The scheduled termination date of Mr. Fundaro's plan is March 26, 2015. Sales under the plan may be executed earlier than the scheduled termination date or may not be executed to the full amount. Transactions made under Mr. Fundaro's plan will be publicly disclosed through filings with the U.S. Securities and Exchange Commission under Section 16 of the Exchange Act. Except as may be required by law, we do not undertake to report on specific Rule 10b5-1 pre-planned stock trading plans of our directors and officers, nor to report modifications or terminations of the aforementioned plans or the plan of any other individual.

Item 6. Exhibits.

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

SIGNATURES

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

INTERCEPT PHARMACEUTICALS, INC.

Date: November 6, 2014 By: /s/ Mark Pruzanski, M.D.
Mark Pruzanski
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 6, 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).
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 September 30, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at December 31, 2013 and September 30, 2014 (unaudited), (ii) Condensed Consolidated Statements of Operations for the three and six month periods ended September 30, 2013 and 2014 (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three month and nine month periods ended September 30, 2013 and 2014 (unaudited), (iv) Condensed Consolidated Statements of Cash Flows for the three and nine month periods ended September 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.