

INTERCEPT PHARMACEUTICALS INC

Form 10-Q

November 06, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

**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)**

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

**(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  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  No

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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

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

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,” “warrant,” “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.





**INTERCEPT PHARMACEUTICALS, INC.****Condensed Consolidated Statements of Operations****(Unaudited)**

	Three Months Ended		Nine Months Ended	
	September 30,		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		Nine Months Ended	
	September 30,		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



**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			
		Gross Unrealized	Gross Unrealized	
	Amortized	Gains	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			
		Gross Unrealized	Gross Unrealized	
	Amortized	Gains	Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	\$ 18,059	\$ -	\$ -	\$ 18,059



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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)**

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

	<b>As of September 30, 2014</b>						
	<b>Less than 12 months</b>		<b>12 Months or greater</b>		<b>Total</b>		
	<b>(In thousands)</b>						
	<b>Fair Value</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>	<b>Gross Unrealized Losses</b>	
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:

-

**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)**

	<b>Fair Value Measurements Using</b>			
	<b>Quoted</b>			
	<b>Prices in</b>			
		<b>Significant</b>		<b>Significant</b>
	<b>Active</b>	<b>Other</b>	<b>Significant</b>	
	<b>Markets</b>	<b>Observable</b>	<b>Unobservable</b>	
	<b>for</b>	<b>Inputs</b>	<b>Inputs</b>	
	<b>Identical</b>	<b>Inputs</b>	<b>(Level 3)</b>	
	<b>Assets or</b>	<b>Liabilities</b>	<b>(Level 2)</b>	
	<b>(Level 1)</b>			
	<b>(In thousands)</b>			
<b>December 31, 2013</b>				
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)
<b>September 30, 2014</b>				
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.

	<b>Warrant Liability</b> (In thousands)
<b>Level 3</b>	
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:

	<b>Fair Value as of</b>	
	<b>December 31,</b>	<b>September 30,</b>
	<b>2013</b>	<b>2014</b>
	(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



**INTERCEPT PHARMACEUTICALS, INC.**

**Notes to Condensed Consolidated Financial Statements**

**(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		Nine Months Ended	
	September 30,		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.

**INTERCEPT PHARMACEUTICALS, INC.****Notes to Condensed Consolidated Financial Statements****(Unaudited)**

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 )

**INTERCEPT PHARMACEUTICALS, INC.****Notes to Condensed Consolidated Financial Statements****(Unaudited)**

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.

**INTERCEPT PHARMACEUTICALS, INC.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

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