INTERCEPT PHARMACEUTICALS INC
Form 10-Q
May 11, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

OR

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

For the transition period from to

Commission file number: 001-35668

INTERCEPT PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(646) 747-1000

(Registrant's Telephone Number, Including Area Code)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting

company" in Rule 12b-2 of the Exchange Act.

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

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

As of April 30, 2015, there were 24,072,311 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,” “potential,” “will,” “wou “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;
- the timing of and our ability to obtain and maintain regulatory approval of obeticholic acid, or OCA, and any other product candidates we may develop, particularly the possibility that regulatory authorities may require clinical outcomes data (and not just results based on achievement of a surrogate endpoint) as a condition to any marketing approval for OCA, and any related restrictions, limitations and/or warnings in the label of any approved product candidates;
- our plans to research, develop and commercialize our product candidates;
- our collaborators’ election to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to successfully commercialize our product candidates;
- the size and growth of the markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers;
- our need for and ability to obtain additional financing;
- our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof;
- our use of the proceeds from our initial public offering in October 2012 and our follow-on public offerings in June 2013, April 2014, February 2015 and April 2015; and
- our ability to attract and retain key scientific or management personnel.

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

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

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

NON-GAAP FINANCIAL MEASURES

This Quarterly on Form 10-Q presents projected adjusted operating expense, which is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP, and should be considered in addition to, but not as a substitute for, operating expense that we prepare and announce in accordance with GAAP. We exclude certain items from adjusted operating expense, such as stock-based compensation and other non-cash items, that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. We anticipate that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under GAAP. A reconciliation of projected non-GAAP adjusted operating expense to operating expense calculated in accordance with GAAP is not available on a forward-looking basis without unreasonable effort due to an inability to make accurate projections and estimates related to certain information needed to calculate, for example, future stock-based compensation expense. Management also uses adjusted operating expense to establish budgets and operational goals and to manage our company’s business. Other companies may define this measure in different ways. We believe this presentation provides investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

PART I

Item 1. FINANCIAL STATEMENTS

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

	December 31, 2014 (Audited)	March 31, 2015 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$20,022,927	$104,366,238
Investment securities, available-for-sale	219,700,890	297,626,140
Prepaid expenses and other current assets	6,104,017	8,392,121
Total current assets	245,827,834	410,384,499
Fixed assets, net	5,851,756	7,531,251
Security deposits	2,469,343	3,726,964
Total assets	$254,148,933	$421,642,714
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$13,459,489	$16,371,058
Short-term portion of deferred revenue	1,781,620	1,781,620
Total current liabilities	15,241,109	18,152,678
Long-term liabilities:		
Long-term portion of deferred revenue	8,017,301	7,571,896
Total liabilities	23,258,410	25,724,574
Stockholders' equity:		
Common stock. 35,000,000 shares authorized; 21,415,243 and 22,706,973 shares issued and outstanding as of December 31, 2014 and March 31, 2015, respectively; par value $0.001 per share	21,415	22,707
Additional paid-in capital	700,354,657	904,714,141
Accumulated other comprehensive income (loss), net	(283,835)	(230,873)
Accumulated deficit	(469,201,714)	(508,587,835)
Total stockholders' equity	230,890,523	395,918,140
Total liabilities and stockholders' equity	$254,148,933	$421,642,714

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 March 31,	
	2014	2015
Licensing revenue	$405,403	$1,445,405
Costs and expenses:		
Research and development	14,292,693	27,965,634
General and administrative	5,651,127	13,137,816
Total costs and expenses	19,943,820	41,103,450
Other income (expense):		
Revaluation of warrants	(226,626,668)	-
Other income, net	136,257	271,925
	(226,490,411)	271,925
Net loss	$(246,028,828)	$(39,386,120)
Net loss per share:		
Basic and diluted	$(12.61)	$(1.78)
Weighted average shares outstanding:		
Basic and diluted	19,504,748	22,171,988

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended March 31,	
	2014	2015
Net loss	$(246,028,828)	$(39,386,120)
Other comprehensive loss:		
Unrealized losses on securities:		
Unrealized holding gains (losses) arising during the period	(43,484)	212,618
Reclassification for recognized gains on marketable investment securities during the period	-	2,367
Net unrealized gains (losses) on marketable investment securities	$(43,484)	$214,985
Foreign currency translation adjustments	(3,533)	(162,023)
	$(47,017)	$52,962
Comprehensive loss	$(246,075,845)	$(39,333,158)

INTERCEPT PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2014	2015
Cash flows from operating activities:		
Net loss	$(246,028,828)	$(39,386,120)
Adjustments to reconcile net loss to net cash used in operating activities:		
Revaluation of warrants	226,626,668	-
Share-based compensation	7,435,652	9,738,093
Depreciation	61,661	250,359
Amortization of investment premium	551,913	883,651
Changes in:		
Prepaid expenses, other current assets and security deposits	(2,064,234)	(3,545,725)
Accounts payable, accrued expenses and other current liabilities	1,504,194	2,911,569
Deferred revenue	(405,402)	(445,405)
Net cash used in operating activities	(12,318,376)	(29,593,578)
Cash flows from investing activities:		
Purchases of investment securities	(15,723,676)	(122,213,831)
Sales of investment securities	23,729,896	43,619,915
Purchases of equipment, improvements, and furniture and fixtures	(299,808)	(1,929,854)
Net cash provided by (used in) investing activities	7,706,412	(80,523,770)
Cash flows from financing activities:		
Proceeds from issuance of stock offerings, net of issuance costs	-	191,633,977
Cost associated with issuance of stock	(338,816)	-
Proceeds from exercise of options	2,798,428	2,988,705
Net cash provided by financing activities	2,459,612	194,622,682
Effect of exchange rate changes	-	(162,023)
Net (decrease) increase in cash and cash equivalents	(2,152,352)	84,343,311
Cash and cash equivalents – beginning of period	13,363,185	20,022,927
Cash and cash equivalents – end of period	$11,210,833	$104,366,238

See accompanying notes to the condensed consolidated financial statements.

1. Nature of Business and Basis of Presentation

Intercept Pharmaceuticals, Inc. (“Intercept” or the “Company”), is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver diseases with high unmet medical need. 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. In February 2015, the Company signed a lease for an office in London, United Kingdom. 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

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

Use of Estimates

The preparation of these financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses, revenues and related disclosures. On an ongoing basis, management evaluates estimates, clinical trial accruals and share-based compensation expense. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under circumstances. Actual results may differ from those estimates or assumptions.

Revision of Prior Period Financial Statements

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

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 3 to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

3. Significant Agreements

Sumitomo Dainippon Pharma Co, Ltd. (Sumitomo Dainippon)

In March 2011, the Company entered into an exclusive license agreement with Sumitomo Dainippon to research, develop and commercialize obeticholic acid (OCA) as a therapeutic for the treatment of primary biliary cirrhosis (PBC) and nonalcoholic steatohepatitis (NASH) in Japan and China (excluding Taiwan). Under the terms of the license agreement, the Company received an up-front payment from Sumitomo Dainippon of $15.0 million and may be eligible to receive additional milestone payments up to an aggregate of approximately $30.0 million in development milestones based on the initiation or completion of clinical trials, $70.0 million in regulatory approval milestones and $200.0 million in sales milestones. The regulatory approval milestones include $15.0 million for receiving marketing approval for OCA for NASH in Japan, $10.0 million for receiving marketing approval for OCA for NASH in China, and up to $5.0 million for receiving marketing approval for OCA for PBC in the United States. As of March 31, 2015, the Company had achieved $1.0 million of the development milestones under its collaboration agreement with Sumitomo Dainippon. The sales milestones are based on aggregate sales amounts of OCA and include $5.0 million for achieving net sales of $50.0 million, $10.0 million for achieving net sales of $100.0 million, $20.0 million for achieving net sales of $200.0 million, $40.0 million for achieving net sales of $400.0 million and $120.0 million for achieving net sales of $1.2 billion. The Company has determined that each potential future development, regulatory and sales milestone is substantive. In May 2014, Sumitomo Dainippon exercised its option under the license agreement to add Korea as part of its licensed territories and paid the Company a $1.0 million up-front fee. Sumitomo Dainippon has the option to add several other Asian countries to its territory to pursue OCA for additional indications. Sumitomo Dainippon will be responsible for the costs of developing and commercializing OCA in its territories Dainippon is also required to make royalty payments ranging from the tens to the twenties in percent based on net sales of OCA products in the Sumitomo Dainippon territory.

The Company evaluated the license agreement with Sumitomo Dainippon and determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company’s substantive performance obligations under this license include an exclusive license to its technology, technical and scientific support to the development plan and participation on a joint steering committee. The Company determined that these performance obligations represent a single unit of accounting, since, initially, the license does not have stand-alone value to Sumitomo Dainippon without the Company’s technical expertise and steering committee participation during the development of OCA. This development period is currently estimated as continuing through June 2020 and, as such, the up-front payment and payments made in respect of the Korea option are being recognized ratably over this period. During the three months ended March 31, 2014 and 2015, the Company recorded revenue of approximately $405,000 and $1.4 million, respectively, in “Licensing Revenue” in its Condensed Consolidated Statement of Operations for the Company’s efforts under the agreement. All of the revenue recognized in the three months ended March 31, 2014 related to the amortization of the up-front payments under the collaboration agreement. For the three months ended March 31, 2015, $445,000 resulted from the amortization of the up-front payments under the collaboration agreement and $1.0 million resulted from the milestone achieved in the period.

United Kingdom Lease

On February 19, 2015, the Company entered into an underlease with Merck Sharp & Dohme Limited for the Company's new office in the King's Cross area of London, United Kingdom. The lease will provide the Company with approximately 6,000 rentable square feet in London for office space. The lease term is anticipated to end in June 2019.

The annual rent is £470,608, payable quarterly. The Company is also required to pay value added tax (VAT) on the rent. The Company will be responsible for a portion of the insurance, certain service charges and taxes for the building based on the floor area rented by the Company. As security for the underlease, the Company has provided the landlord with a rent deposit in the amount of £705,912 (or approximately $1,047,150), plus applicable VAT. The amount of the deposit may be reduced to £470,608 within 30 days after April 30, 2016 if there are no outstanding payments due and there are no material breaches of the underlease that have not been unremedied in respect of which a drawdown notice has been served and has expired.

4. Investments

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

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

	As of March 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	**Fair Value**
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$104,366	$ -	$ -	$ 104,366
Investment securities:				
Commercial paper	10,495	-	(3)	10,492
Corporate debt securities	255,861	34	(127)	255,768
U.S. government and agency securities	31,334	33	(2)	31,366
Total investments	297,691	67	(132)	297,626
Total cash, cash equivalents and investments	$402,057	$ 67	$ (132)	$ 401,992

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

	As of December 31, 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	$86,221	$ (63)	$ 81,561	$ (219)	$167,782	$ (282)
Commercial paper	4,994	(1)	-	-	4,994	(1)
U.S. government and agency securities	-	-	4,481	(16)	4,481	(16)
Total	$91,215	$ (64)	$ 86,042	$ (235)	$177,257	$ (299)

	As of March 31, 2015					
	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	$120,384	$ (74)	$ 57,790	$ (53)	$178,174	$ (127)
Commercial paper	7,493	(3)	-	-	7,493	(3)
U.S. government and agency securities	-	-	4,496	(2)	4,496	(2)
Total	$127,877	$ (77)	$ 62,286	$ (55)	$190,163	$ (132)

5. Income Taxes

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

At December 31, 2014 and March 31, 2015, the Company had available net operating loss carryforwards to reduce future taxable income of approximately $208.9 million and $240.4 million, respectively, for tax reporting purposes. These carryforwards expire between 2024 and 2035. The ability of the Company to utilize its net operating losses in future years is subject to limitation in accordance with provisions of Section 382 of the Internal Revenue Code due to previous ownership changes; however, these changes have not resulted in material limitations to the Company's ability to utilize the net operating losses. The Company's deferred tax asset of approximately $104.7 million and $121.7 million at December 31, 2014 and March 31, 2015, respectively, resulted primarily from the tax effects of net operating losses, share-based compensation and deferred revenue. The Company does not have any deferred tax liabilities. Since the Company has not yet achieved sustained profitable operations, management believes its deferred

tax assets do not satisfy the more-likely-than-not realization criteria and has provided an allowance for the full amount of the tax asset. As a result, the Company has not recorded any income tax benefit since its inception.

6. Warrants to Purchase Common Stock

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

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

7. Fair Value Measurements

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

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

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

- Pricing Models with Significant Observable Inputs — The fair value of an asset or liability is based on information derived from either an active market quoted price, which may require further adjustment based on the attributes of the financial asset or liability being measured, or an inactive market transaction (Level 2).
- Pricing Models with Significant Unobservable Inputs — The fair value of an asset or liability is primarily based on internally derived assumptions surrounding the timing and amount of expected cash flows for the financial

instrument. Therefore, these assumptions are unobservable in either an active or inactive market (Level 3).

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

The Company’s cash deposits and money market funds are classified within Level 1 of the fair value hierarchy because they are valued using bank balances or quoted market prices. Investments are classified as Level 2 instruments based on market pricing or other observable inputs. None of the Company’s investments are classified within Level 3 of the fair value hierarchy. The Company’s previous outstanding warrant liability was valued pursuant to the discussion in note 6 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:

	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, 2014				
Assets:				
Money market funds	$21,284	$21,284	$ -	$ -
Available for sale securities:				-
Commercial paper	7,994	-	7,994	$ -
Corporate debt securities	203,725	-	203,725	-
U.S. government and agency securities	7,982	-	7,982	-
Total financial assets:	$240,985	$21,284	$ 219,701	$ -
March 31, 2015				
Assets:				
Money market funds	$81,343	$81,343	$ -	$ -
Available for sale securities:				
Commercial paper	10,492	-	10,492	-
Corporate debt securities	255,768	-	255,768	-
U.S. government and agency securities	31,366	-	31,366	-
Total financial assets	$378,969	$81,343	$ 297,626	$ -

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, 2014	March 31, 2015
	(In thousands)	
Due in one year or less	$130,159	$ 179,572
Due after 1 year through 2 years	89,542	118,054
Total investments in debt securities	$219,701	$ 297,626

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

Common Stock

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

In October 2012, the Company completed the IPO of its common stock pursuant to a registration statement on Form S-1. In the IPO, the Company sold an aggregate of 5,750,000 shares of common stock under the registration statement at a public offering price of $15.00 per share. Net proceeds were approximately $78.7 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all outstanding shares of the Company's preferred stock (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 pursuant to a registration statement on Form S-1. Net proceeds were approximately $61.2 million, after deducting underwriting discounts and commissions and offering expenses 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 pursuant to a registration statement on Form S-3. After underwriting discounts and commissions and offering expenses, the Company received net proceeds from the offering of approximately $183.5 million. The Company did not receive any proceeds from the sale of shares of common stock by the selling stockholders.

In February 2015, the Company completed a public offering of 1,150,000 shares of its common stock pursuant to a registration statement on Form S-3. After underwriting discounts and commissions and estimated offering expenses, the Company received net proceeds of approximately $191.6 million.

In April 2015, the Company completed a public offering of 1,330,865 shares of its common stock pursuant to a registration statement on Form S-3. After estimated offering expenses, the Company received net proceeds of approximately $366.8 million. As the April 2015 financing occurred after March 31, 2015, this transaction is not reflected on the Condensed Consolidated Balance Sheet.

8. Stock-Based Compensation

The 2012 Equity Incentive Plan (2012 Plan) became effective upon the pricing of the IPO in October 2012. At the same time, the 2003 Stock Incentive Plan (2003 Plan) was terminated and 555,843 shares available under the 2003 Plan were added to the 2012 Plan.

The estimated fair value of the options that have been granted under the 2003 and 2012 Plans is determined utilizing the Black-Scholes option-pricing model at the date of grant. The fair value of restricted stock units (RSUs) and restricted stock awards (RSAs) that have been granted under the 2012 Plan is determined utilizing the closing stock price on the date of grant.

The following table summarizes stock option activity during the three months ended March 31, 2015:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2014	1,436,055	$ 75.81
Granted	17,037	$ 182.50
Exercised	(115,274)	$ 25.93
Forfeited	(48,277)	$ 100.14
Outstanding, March 31, 2015	1,289,541	$ 80.77
Exercisable, March 31, 2015	676,425	$ 31.59

The following table summarizes the aggregate activities in relation to RSU and RSA activity during the three months ended March 31, 2015:

	Number of Shares	Weighted Average Fair Value	Aggregate Intrinsic Value
Outstanding, December 31, 2014	119,348	$ 133.60	$18,618,288
Granted	19,067	$ 229.02	$4,026,673
Exercised	(15,610)	$ 101.52	$2,495,838
Forfeited	(3,630)	$ 257.43	$1,044,364
Outstanding, March 31, 2015	119,175	$ 149.30	$33,609,734

As of March 31, 2015, there was $14.6 million of unrecognized compensation expense related to unvested RSUs and RSAs, which is expected to be recognized over a weighted average of 2.83 years. The weighted average remaining contract life of the non-vested shares as of March 31, 2015 is 8.76 years.

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

	Number of Shares	Price	Intrinsic Value (in thousands)
Employees and directors	105,297	$21.50 - $288.21	$ 29,696
Consultants	13,878	$21.50 - $290.98	3,914
Outstanding at March 31, 2015	119,175		$ 33,610

9. Net Loss Per Share

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

	Three Months Ended March 31,	
	2014	2015
	(In thousands, except share and per share amounts)	
Historical net loss per share		
Numerator:		
Net loss attributable to common stockholders	$ (246,029)	$ (39,386)
Denominator:		
Weighted average shares used in calculating net loss per share - basic and diluted	19,504,748	22,171,988

Net loss per share: Basic and diluted	$ (12.61)	$ (1.78)

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

	As of March 31,	
	2014	2015
	(In thousands)	
Options	1,483	1,290
Warrants to purchase common stock	865	-
Restricted stock units	105	119
Total	2,453	1,409

10. Litigation

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

The lawsuits allege that the Company made material misrepresentations and/or omissions of material fact in its public disclosures during the period from January 9, 2014 to January 10, 2014, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to the Company's January 9, 2014 announcement that the FLINT trial had been stopped early based on a pre-defined interim efficacy analysis. Specifically, the lawsuits claim that the January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo. On April 22, 2014, two individuals each moved to consolidate the cases and a lead plaintiff was subsequently appointed by the Court. On June 27, 2014, the lead plaintiff filed an amended complaint on behalf of the putative class as contemplated by the order of the Court. On August 14, 2014, the defendants filed a motion to dismiss the complaint. Oral arguments on the motion to dismiss were held on February 24, 2015. On March 4, 2015, the defendants' motion to dismiss was denied by the Court. The defendants answered the amended complaint on April 13, 2015. The parties are currently undergoing discovery in relation to this matter.

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

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

The Company may become subject to claims and assessments from time to time in the ordinary course of business. Such matters are subject to uncertainties and outcomes are not predictable with assurance. The Company accrues liabilities for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of March 31, 2015, the Company does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial condition, results of operations or cash flows.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2014 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2015. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Item 1.A. "Risk Factors" of our Annual Report on Form 10-K and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver diseases. Our product candidates have the potential to treat orphan and more prevalent liver diseases for which there currently are limited therapeutic solutions.

Our lead product candidate, obeticholic acid, or OCA, selectively binds to and activates the farnesoid X receptor, or FXR, which we believe has broad liver-protective properties. OCA has been tested in five placebo-controlled clinical trials, including a Phase 3 clinical trial in patients with primary biliary cirrhosis, or PBC, and two Phase 2 clinical trials in patients with nonalcoholic fatty liver disease, or NAFLD, and nonalcoholic steatohepatitis, or NASH. OCA met the primary efficacy endpoint in each of these trials with statistical significance.

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

Our most advanced development program for OCA is for PBC as a second line treatment for patients who have an inadequate response to the current standard of care or as monotherapy for those who are unable to tolerate standard of care therapy and therefore need additional treatment. PBC is a chronic autoimmune liver disease that, if inadequately treated, may eventually lead to cirrhosis, liver failure and death. In March 2014, we completed a Phase 3 clinical trial,

known as the POISE trial, in which OCA achieved the primary endpoint for the treatment of PBC. We intend to use these results, along with two previously completed randomized Phase 2 clinical trials of OCA in PBC, as the basis for seeking the first regulatory approvals to market OCA in the United States, Europe, Canada and Australia. We initiated a rolling New Drug Application, or NDA, submission with the FDA for OCA in PBC in December 2014 under the FDA's accelerated approval pathway. We plan to complete our filings for marketing approval of OCA in PBC in the United States and Europe during the first half of 2015. We also plan to apply for marketing approval of OCA in PBC in other markets such as Canada and Australia. If we receive marketing approval from regulatory authorities, we plan to initiate the commercial launch of OCA in PBC in the United States, certain European countries and Canada in 2016.

OCA achieved the primary endpoint in a Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, which was sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health. The FLINT trial was completed in July 2014. We are planning to finalize the design of our Phase 3 clinical program in NASH in the second quarter of 2015, subject to the completion of our regulatory discussions with the FDA and European Medicines Agency, or EMA, and then initiate the clinical program. We also intend to initiate a clinical trial in 2015 characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. Our collaborator, Sumitomo Dainippon Pharma Co. Ltd., or Sumitomo Dainippon, has completed enrollment in a 200-patient Phase 2 NASH clinical trial of OCA in Japan with a primary efficacy endpoint similar to that used in our Phase 2b FLINT trial, which is anticipated to be completed by the end of 2015.

Our net loss for the three months ended March 31, 2014 and 2015 was approximately $246.0 million and $39.4 million, respectively. As of March 31, 2015, we had an accumulated deficit of approximately $508.6 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations and, for the three months ended March 31, 2014, from the mark-to-market of our previously outstanding liability-classified warrants.

In April 2015, we completed a follow-on public offering of 1,330,865 shares of our common stock. After offering expenses, we estimate that the net proceeds from our April 2015 follow-on equity offering were approximately $366.8 million.

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

- complete the development of our lead product candidate, OCA, for the treatment of PBC, and continue the development of OCA in NASH, PSC and other patient populations;
- seek to obtain regulatory approvals for OCA for PBC, NASH and other potential patient populations;
- prepare for the potential commercialization of OCA in PBC, including establishing our sales, marketing and distribution capabilities and increasing our drug manufacturing activities;

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- continue development of our other product candidates, such as INT-767, and engage in other research and development activities;
- maintain, expand and protect our intellectual property portfolio;
- increase our product development, scientific, commercial and administrative personnel and expand our facilities and operations in the United States and abroad; and
- operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital to commercialize OCA on a worldwide basis and continue our research and development activities in relation to OCA and our other pipeline candidates. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

We have an administrative headquarters in New York, New York and an office in San Diego, California. In February 2015, we signed a lease for an office in London, United Kingdom. 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. We have entered into an exclusive licensing agreement with Sumitomo Dainippon for the development of OCA in Japan, China and Korea. Under the terms of the agreement, we have received up-front payments of $16.0 million, including $1.0 million upon the exercise by Sumitomo Dainippon of its option to add Korea to its licensed territories, and may be eligible to receive up to approximately $300 million in additional payments for development, regulatory and commercial sales milestones for OCA in the licensed territories. As of March 31, 2015, we have achieved $1.0 million of the development milestones.

For accounting purposes, the up-front payments are recorded as deferred revenue and amortized over time and milestone payments are recognized once earned. We recognized $405,000 and $1.4 million in license revenue for the three months ended March 31, 2014 and 2015, respectively. All of the revenue recognized in the three months ended March 31, 2014 related to the amortization of the up-front payments under the collaboration agreement. For the three months ended March 31, 2015, $445,000 resulted from the amortization of the up-front payments under the collaboration agreement and $1.0 million resulted from the milestone achieved in the period. We anticipate that we will recognize revenue of approximately $1.8 million per year through 2020, for the amortization of the relevant up-front collaboration payments from Sumitomo Dainippon. In the future, we may generate revenue from a combination of license fees and other up-front payments, research and development payments, milestone payments, product sales and royalties in connection with our collaborations. We expect that any revenue we generate will fluctuate from quarter-to-quarter as a result of the timing of our achievement of preclinical, clinical, regulatory and commercialization milestones, if at all, the timing and amount of payments relating to such milestones and the extent to which any of our products are approved and successfully commercialized by us or our collaboration partners. If our collaboration partners fail to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of direct costs, personnel costs and indirect costs such as the following:

Direct costs:

- fees paid to consultants and clinical research organizations, or CROs, including in connection with our preclinical 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 activities associated with acquiring and manufacturing OCA;
- costs associated with discovery and early stage research initiatives; and
- costs related to compliance with regulatory requirements.

Personnel costs:

- salaries and related benefit expenses for personnel in research and development functions; and
- costs related to stock compensation granted to personnel in research and development functions.

Indirect costs:

- rent and other facilities-related costs; and
- product-related legal costs.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of OCA for the treatment of PBC, NASH and PSC and other indications and to further advance the development of our other product candidates, subject to the availability of additional funding.

The table below summarizes our direct research and development expenses by program for the periods indicated. We do not allocate personnel costs and indirect costs related to our research and development function to specific product candidates. Those expenses are included in personnel costs and indirect research and development expense in the table below.

	Three Months Ended March 31,	
	2014	2015
	(In thousands)	
Direct research and development expense by program:		
OCA	$ 4,909	$ 8,958
Research and discovery initiatives	–	3,626
INT-767	684	1,789
Total direct research and development expense	5,593	14,373
Personnel costs (1)	8,008	12,386
Indirect research and development expense	691	1,207
Total research and development expense	$ 14,293	$ 27,966

(1) Personnel costs include stock options and restricted stock awards granted to employees and non-employees with an associated stock-based compensation expense of $5.9 million and $6.0 million for the three months ended March 31, 2014 and 2015, respectively. During the quarter ended March 31, 2015, we added 32 research and development personal in support of our expansion activities.

The successful development of our clinical and preclinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our clinical or preclinical product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future clinical trial results; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

OCA

The majority of our research and development resources are focused on completing our NDA and Marketing Authorization Application, or MAA, filings for OCA for the treatment of PBC, which we currently plan to complete during the second quarter of 2015. We have incurred and expect to continue to incur significant expenses in connection with these efforts, including:

- We completed our POISE trial of OCA in patients with PBC in March 2014 and expect to continue the long-term safety extension phase of the trial through 2019.
- We initiated our clinical outcomes confirmatory trial for OCA in PBC in December 2014 and expect the trial to be completed on a post-marketing basis.
- We conducted numerous Phase 1 clinical trials during 2014 in support of the anticipated NDA and MAA filings for OCA in PBC.
- 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 are building commercial supplies, including supplies of the starting material for manufacturing OCA.
- We have contracted with and plan to engage a number of consultants and other third party vendors in relation to our seeking of regulatory approval and have implemented and will implement various electronic software and systems in relation to our regulatory activities.

In addition, we are evaluating OCA in other chronic liver diseases, particularly NASH and PSC. We expect to complete regulatory discussions regarding the Phase 3 trial design for our NASH program in the second quarter of 2015 and subsequently initiate the trial. We are also planning a clinical trial characterizing lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. For PSC, we initiated a Phase 2 clinical trial in December 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 (a selective TGR5 agonist). 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 around year end 2015. We also intend to conduct additional preclinical work on INT-777 to further characterize its therapeutic potential.

Other than OCA, our product development programs are at 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 and operational functions, including sales and marketing, finance, information technology, legal and human resources. Other significant general and administrative expenses include non-cash stock-based compensation expenses, expenses related to our OCA pre-commercialization activities, facilities costs, accounting and legal services, information technology and other expense of operating as a public company.

Our general and administrative expenses have increased and will continue to increase as we operate as a public company and due to the potential commercialization of our product candidates. We further plan on expanding our operations both in the United States, Europe and other countries such as Canada and Australia, which will increase our general and administration expenses. We believe that these activities will result in increased costs related to the hiring of significant additional personnel, increased fees for outside consultants, lawyers and accountants and the addition of facilities. We have also incurred and will continue to incur increased costs to comply with corporate governance, internal controls, compliance and similar requirements applicable to public companies with expanding operations and biopharmaceutical companies seeking to commercialize its product candidates. During the quarter ended March 31, 2015, we added 29 corporate and commercial personnel in support of our expansion in activities.

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.

Revaluation of Warrants

In conjunction with various financing transactions prior to our initial public offering, we issued warrants to purchase shares of our common stock. As of March 31, 2015, all of the warrants have either been exercised or expired in accordance with their terms. Certain of the warrants that were outstanding during 2014 included a provision that provided for a reduction in the warrant exercise price upon subsequent issuances of additional shares of common stock for consideration per share less than the applicable per share warrant exercise price. The warrants containing this provision were deemed to be derivative instruments and as such, were recorded as a liability and marked-to-market at each reporting period. The fair value estimates of these warrants were determined using a Black-Scholes option-pricing model and were based, in part, on subjective assumptions. Non-cash changes in the fair value of the common stock warrant liability from the prior period were recorded as a component of other income and expense.

Results of Operations

Comparison of the Three Months Ended March 31, 2014 and the Three Months Ended March 31, 2015

The following table summarizes our results of operations for each of the three months ended March 31, 2014 and 2015, together with the changes in those items in dollars:

	Three Months Ended March 31,		Dollar Change
	2014	2015	
	(In thousands)		
Licensing revenue	$405	$1,445	$ 1,040
Operating expenses:			
Research and development	14,292	27,966	13,673
General and administrative	5,651	13,138	7,487
Loss from operations	(19,538)	(39,658)	(20,120)
Warrant revaluation (expense)	(226,627)	–	226,627
Other income, net	136	272	136
Net loss	$(246,029)	$(39,386)	$ 206,643

Licensing Revenue

Licensing revenue was $405,000 and $1.4 million for the three months ended March 31, 2014 and 2015, respectively. All of the revenue recognized in the three months ended March 31, 2014 related to the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon. For the three months ended March 31, 2015, $445,000 resulted from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon and $1.0 million resulted from the milestone achieved in the period.

Research and Development Expenses

Research and development expenses were $14.3 million and $28.0 million for the three months ended March 31, 2014 and 2015, respectively, representing an increase of $13.7 million. This increase in research and development expense primarily reflects:

- increased expenses of $7.8 million related to personnel and activities to support our anticipated NDA and MAA filings for OCA in PBC;
- increased research and discovery initiatives of approximately $3.8 million;
- increased costs of $1.1 million associated with our INT-767 program;
- increased product development and manufacturing costs of approximately $500,000; and
- increased indirect costs of approximately $500,000.

General and Administrative Expenses

General and administrative expenses were $5.7 million and $13.1 million in the three months ended March 31, 2014 and 2015, respectively. The $7.4 million increase primarily reflects:

- increased compensation and benefit costs, primarily due to increase in personnel, of approximately $2.6 million;
- increased non-cash stock-based compensation expense of approximately $2.3 million;
- increased expenses of approximately $1.9 million related to legal, finance, and facilities costs to support our growing operations; and
- increased expenses from pre-commercial activities of approximately $600,000.

Other Income, Net

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which increased compared to the prior year period as a result of the increase in the investment balances from our April 2014 and February 2015 equity financing. We expect interest income to increase in future periods as we invest the proceeds from our February and April 2015 equity financings.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2015, we had an accumulated deficit of $508.6 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

We have funded our operations primarily through the sale of common stock, preferred stock, convertible notes and warrants and payments received under our collaboration agreements totaling $622.7 million (net of issuance costs of $33.7 million), including $29.7 million in net proceeds from our Series C financing in August 2012, $78.7 million in net proceeds from our initial public offering in October 2012, $61.2 million in net proceeds from our follow-on public offering in June 2013, $183.5 million in net proceeds from a follow-on public offering in April 2014, $191.6 million in net proceeds from a follow-on public offering in February 2015 and the receipt of $17.4 million in up-front

payments under our licensing and collaboration agreements with Sumitomo Dainippon and Servier. As of March 31, 2015, we had cash, cash equivalents and investment securities of $402.0 million. In April 2015, we completed a follow-on public offering of 1,330,865 shares. After offering expenses, we estimate that the net proceeds from our April 2015 follow-on equity offering were approximately $366.8 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in cash and money market bank accounts and investments, all of which have maturities of less than two years.

Cash Flows

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

	Three Months Ended March 31,	
	2014	2015
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (12,318)	$ (29,594)
Investing activities	7,706	(80,524)
Financing activities	2,460	194,623
Effect of exchange rate changes	-	(162)
Net (decrease) increase in cash and cash equivalents	$ (2,152)	$ 84,343

Operating Activities. The increase in our net cash used in operating activities of approximately $17.3 million during the three months ended March 31, 2015 as compared to the same period last year was primarily a result of our increased activities in our business requiring more capital. Net cash used in operating activities of $12.3 million during the three months ended March 31, 2014 was primarily a result of our $246.0 million net loss, offset by the add-back of non-cash expenses of $7.4 million for stock-based compensation, $226.6 million for warrant liability revaluation, the amortization of investment premium of $552,000 and net changes in operating assets and liabilities of $1.0 million. Net cash used in operating activities of $29.6 million during the three months ended March 31, 2015 was primarily a result of our $39.4 million net loss, offset by the add-back of non-cash expenses of $9.7 million for stock-based compensation, the amortization of investment premium of $884,000 and net changes in operating assets and liabilities of $1.0 million.

Investing Activities. Net cash provided by investing activities for the three months ended March 31, 2014 was $7.7 million as compared to net cash used in investing activities of $80.5 million during the same period in 2015. This net increase in cash used in investing activities of approximately $88.2 million is attributed to the increase in the purchases of investments of $106.5 million as a result of investing the proceeds from the February 2015 offering offset by the increase in the sale of investments of $19.9 million. The increase in purchases of equipment, improvements, and furniture and fixtures of approximately $1.6 million is primarily related to our expansion efforts at our New York office and the initiation of leasehold improvements in our UK office.

Financing Activities. Net cash provided by financing activities for the three months ended March 2014 were $2.5 million compared to $194.6 million for the comparable period in 2015. This increase was primarily the result of funds received through the completion of the February 2015 offering.

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, Europe and in other countries such as Canada and Australia. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

As of March 31, 2015, we had $402.0 million in cash, cash equivalents and investment securities. We estimate that the net proceeds from our April 2015 follow-on equity offering were approximately $366.8 million after estimated

offering expenses. We currently project adjusted operating expenses in the range of $180 million to $200 million in the fiscal year ending December 31, 2015, which excludes stock-based compensation and other non-cash items. These expenses are planned to support the clinical development program for OCA in PBC, NASH and PSC, the expansion of our clinical, regulatory, medical affairs and commercial infrastructure in the United States, Europe and other countries such as Canada and Australia, increased OCA manufacturing activities, as well as the continued development of INT-767 and other preclinical pipeline programs. We anticipate that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under U.S. generally accepted accounting principles, or GAAP. Adjusted operating expense is a financial measure not calculated in accordance with GAAP. See “Non-GAAP Financial Measures” for more information. Accordingly, we will continue to require substantial additional capital to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialization of our products under development.

Due to the many variables inherent to the development and commercialization of novel therapies and our rapid growth and expansion, we currently cannot accurately and precisely predict the duration beyond 2015 over which we expect our cash and cash equivalents (including the estimated net proceeds from our April 2015 follow-on equity offering) to be sufficient to fund our operating expenses and capital expenditure requirements. However, we currently believe that our cash and cash equivalents, including the estimated net proceeds from our April 2015 follow-on equity offering, will be sufficient for us to:

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

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

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

- the willingness of the FDA and the EMA to accept the POISE trial, which is our completed Phase 3 clinical trial for PBC, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for the review and marketing approval of OCA for PBC;
- the progress, costs, results of and timing of our recently initiated confirmatory clinical outcomes trial of OCA for the treatment of PBC, the completion of which we expect will not be a condition to the receipt of marketing approval in the United States or the European Union;
- the design of our planned Phase 3 clinical program for OCA in NASH and the progress, costs, results of and timing of the Phase 3 program and other supporting trials and studies necessary to support anticipated filings for marketing approval in NASH, including the sufficiency of one pivotal clinical trial for marketing approval and/or the acceptability of a surrogate endpoint for accelerated approval of OCA for the treatment of NASH;
- the progress, costs, results of and timing of clinical development of OCA for other indications, including our Phase 2 trial of OCA in PSC and biliary atresia;
- the significant expansion of our operations, personnel and the size of our company and our need to continue to expand;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development, such as INT-767 and INT-777;
- the ability of our product candidates to progress through pre-clinical and clinical development successfully and in a timely manner;
- the expansion of our research and development activities;
- the costs and timing of commercialization activities, including product sales, marketing and distribution, for any of our product candidates that receive marketing approval;
- the costs associated with securing and establishing manufacturing capabilities and procuring the materials necessary for our product candidates;
- market acceptance of our product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management, scientific and medical, commercial and other qualified personnel and the substantial cost of retaining such additional personnel;
- the effect of competing technological and market developments;
- our plan to expand our operations into Europe and other countries such as Canada and Australia and the manner in which we implement our expansion plan;
- our need to implement and maintain internal systems, software and infrastructure, including those to assist in our financial and reporting, clinical development and commercialization efforts and to support our existing and expanding personnel; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent

that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Contractual Obligations and Commitments

Other than as described below, there have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments” in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2015.

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

Off-Balance Sheet Arrangements

As of March 31, 2015, we did not have any off-balance sheet arrangements as defined under the rules of the Securities and Exchange Commission.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates and there have been no material changes since our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2015.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our disclosure controls are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, are recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of March 31, 2015, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures

were adequate and effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), identified in connection with the evaluation of such internal control, that occurred during the three months ended March 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

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

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

The lawsuits allege that we made material misrepresentations and/or omissions of material fact in our public disclosures during the period from January 9, 2014 to January 10, 2014, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. The alleged improper disclosures relate to our January 9, 2014 announcement that the FLINT trial had been stopped early based on a pre-defined interim efficacy analysis. Specifically, the lawsuits claim that the January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo. On April 22, 2014, two individuals each moved to consolidate the cases and a lead plaintiff was subsequently appointed by the Court. On June 27, 2014, the lead plaintiff filed an amended complaint on behalf of the putative class as contemplated by the order of the Court. On August 14, 2014, the defendants filed a motion to dismiss the complaint. Oral arguments on the motion to dismiss were held on February 24, 2015. On March 4, 2015, the defendants' motion to dismiss was denied by the Court. The defendants answered the amended complaint on April 13, 2015. The parties are currently undergoing discovery in relation to this matter.

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

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

Item 1A. Risk Factors.

There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2014 and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission. For a further discussion of our Risk Factors, refer to the "Risk Factors" discussion contained in such filings.

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

Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold by us during the three months ended March 31, 2015 that were not registered under the Securities Act of 1933, as amended, or Securities Act. Also included is the consideration, if any, received by us for the securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

Between January 1 and March 31, 2015, we did not issue or sell any shares on an unregistered basis.

Purchase of Equity Securities

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

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Item 5. Other Information.

None.

Item 6. Exhibits.

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

SIGNATURES

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

INTERCEPT PHARMACEUTICALS, INC.

Date: May 11, 2015 By: /s/ Mark Pruzanski, M.D.
Mark Pruzanski
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 11, 2015 By: /s/ Barbara Duncan
Barbara Duncan
Chief Financial Officer
(Principal Financial and Accounting Officer)

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Exhibit Index

Exhibit Number	Description of Exhibit
10.1	Services Agreement between Registrant and Lisa Bright, effective as of October 13, 2014.#
10.2	Underlease between the Registrant and Merck Sharp & Dohme Limited, dated February 19, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 25, 2015).
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 March 31, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at December 31, 2014 and March 31, 2015 (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three month periods ended March 31, 2014 and 2015 (unaudited), (iii) Condensed Consolidated Statements of Cash Flows for the three month periods ended March 31, 2014 and 2015 (unaudited) and (iv) Notes to Condensed Consolidated Financial Statements (unaudited).

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Management or director compensation plan or policy.