INTERCEPT PHARMACEUTICALS INC
Form 10-Q
November 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from to

Commission file number: 001-35668

INTERCEPT PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

(646) 747-1000

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

As of October 31, 2016, there were 24,808,777 shares of common stock, $0.001 par value per share, outstanding.

Intercept Pharmaceuticals, Inc.

INDEX

Unless the context otherwise indicates, references in this Quarterly Report on Form 10-Q to “we,” “our,” “us” and “the Company” refer, collectively, to Intercept Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries.

FORWARD-LOOKING STATEMENTS

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

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

- our ability to successfully commercialize Ocaliva® (obeticholic acid, or OCA) in primary biliary cholangitis, or PBC, and our ability to maintain our regulatory approval of Ocaliva in PBC in the United States;
- 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 OCA in PBC in countries outside the United States and in indications other than PBC and regulatory approval of any other product candidates we may develop such as INT-767;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our product candidates, such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), and any related restrictions, limitations and/or warnings in the label of any approved product candidates;
- our plans to research, develop and commercialize our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to successfully commercialize OCA in indications other than PBC and our other 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, which may be affected by the reimbursement that our products receive from payors;
- the success of competing drugs that are or become available;
- the election by our collaborators to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- regulatory developments in the United States and other countries;
- the performance of our third-party suppliers and manufacturers;
- our need for and ability to obtain additional financing;
- our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof;
- our use of our cash and short term investments; and
- our ability to attract and retain key scientific or management personnel.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 29, 2016, particularly in Item 1.A. Risk Factors, and in our subsequent periodic and current reports filed with the Securities and Exchange Commission, including those filed in this Quarterly Report on Form 10-Q. Those risk factors, together with any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

NON-GAAP FINANCIAL MEASURES

This Quarterly Report on Form 10-Q presents projected adjusted operating expense, which is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP, and should be considered in addition to, but not as a substitute for, operating expense that we prepare and announce in accordance with GAAP. We exclude certain items from adjusted operating expense, such as the $45.0 million net expense for the settlement of the purported securities class action lawsuit, 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. Other than the net class action lawsuit settlement amount, which is a one-time expense, 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.

NOTE REGARDING TRADEMARKS

The Intercept Pharmaceuticals® name and logo and the Ocaliva® name and logo are either registered or unregistered trademarks or trade names of Intercept Pharmaceuticals, Inc. in the United States and/or other countries. All other trademarks, service marks or other tradenames appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I

Item 1. FINANCIAL STATEMENTS

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets

(Unaudited)
(In thousands, except per share data)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 105,216	$ 32,742
Investment securities, available-for-sale	674,743	595,313
Prepaid expenses and other current assets	14,622	13,638
Total current assets	794,581	641,693
Fixed assets, net	11,865	10,047
Security deposits	5,821	4,018
Total assets	$ 812,267	$ 655,758
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$ 46,854	$ 45,591
Short-term interest payable	3,738	-
Short-term portion of deferred revenue	3,935	1,782
Total current liabilities	54,527	47,373
Long-term liabilities:		
Long-term debt	337,898	-
Long-term portion of deferred revenue	4,899	6,236
Total liabilities	397,324	53,609
Stockholders' equity:		
Common stock par value $0.001 per share; 45,000,000 and 35,000,000 shares authorized; 24,790,952 and 24,391,430 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively.	25	24
Additional paid-in capital	1,406,260	1,300,008
Accumulated other comprehensive loss, net	(2,924)	(2,253)
Accumulated deficit	(988,418)	(695,630)
Total stockholders' equity	414,943	602,149
Total liabilities and stockholders' equity	$ 812,267	$ 655,758

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations

(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Product revenue, net	$4,732	$-	$4,807	$-
Licensing revenue	445	445	6,336	2,336
Total revenue	5,177	445	11,143	2,336
Operating expenses:				
Research and development	43,838	27,487	122,592	83,747
Selling, general and administrative	44,375	24,742	177,082	58,854
Total operating expenses	88,213	52,229	299,674	142,601
Operating loss	(83,036)	(51,784)	(288,531)	(140,265)
Other income (expense):				
Interest expense	(7,065)	-	(7,065)	-
Other income, net	1,286	889	2,807	2,090
	(5,779)	889	(4,258)	2,090
Net loss	$(88,815)	$(50,895)	$(292,789)	$(138,175)
Net loss per common and potential common share:				
Basic and diluted	$(3.59)	$(2.10)	$(11.90)	$(5.89)
Weighted average common and potential common shares outstanding:				
Basic and diluted	24,738	24,215	24,614	23,472

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	$(88,815)	$(50,895)	$(292,789)	$(138,175)
Other comprehensive loss:				
Unrealized losses on securities:				
Unrealized holding losses arising during the period	(1,073)	(25)	966	(707)
Reclassification for recognized gains (losses) on marketable investment securities during the period	-	-	(52)	2
Net unrealized losses on marketable investment securities	$(1,073)	$(25)	$914	$(705)
Foreign currency translation adjustments	(691)	(690)	(1,585)	(514)
Comprehensive loss	$(90,579)	$(51,610)	$(293,460)	$(139,394)

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (292,789)	$ (138,175)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	27,041	22,038
Depreciation	2,187	1,059
Realized gain on investments	52	-
Amortization of deferred financing costs	326	-
Accretion of debt discount	3,001	-
Amortization of investment premium	3,736	4,517
Changes in operating assets:		
Prepaid expenses and other current assets	(984)	(727)
Security deposits	(1,803)	(1,532)
Changes in operating liabilities:		
Accounts payable, accrued expenses and other current liabilities	1,699	16,942
Interest payable	3,738	-
Deferred revenue	817	(1,336)
Net cash used in operating activities	(252,979)	(97,214)
Cash flows from investing activities:		
Purchases of investment securities	(443,323)	(559,928)
Sales of investment securities	361,019	151,053
Purchases of equipment, leasehold improvements, and furniture and fixtures	(4,005)	(5,414)
Net cash used in investing activities	(86,309)	(414,289)
Cash flows from financing activities:		
Proceeds from issuance of stock offerings, net of issuance costs	-	558,756
Payments for capped call transactions and associated costs	(38,364)	-
Proceeds from issuance of Convertible Notes, net of issuance costs	447,715	-
Proceeds from exercise of options	4,429	5,595
Net cash provided by financing activities	413,780	564,351
Effect of exchange rate changes	(2,018)	(514)
Net increase in cash and cash equivalents	72,474	52,334
Cash and cash equivalents – beginning of period	32,742	20,023
Cash and cash equivalents – end of period	$ 105,216	$ 72,357

See accompanying notes to the condensed consolidated financial statements.

8

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 non-viral, progressive liver diseases, including primary biliary cholangitis (“PBC”), nonalcoholic steatohepatitis (“NASH”), primary sclerosing cholangitis (“PSC”) and biliary atresia. Founded in 2002 in New York, Intercept now has operations in the United States, Europe and Canada.

Basis of Presentation

The Company’s financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”). All intercompany accounts and transactions have been eliminated. Certain information that is normally required by U.S. GAAP has been condensed or omitted in accordance with rules and regulations of the Securities and Exchange Commission (“SEC”). Operating results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2016.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2015, included in the Company’s 2015 Annual Report on Form 10-K filed with the SEC.

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. Significant estimates include: clinical trial accruals, revenues and share-based compensation expense. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 3 to the Consolidated Financial Statements included in the Company's 2015 Annual Report on Form 10-K filed with the SEC.

Revenue Recognition

Product Revenue, Net

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. When the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue on the balance sheet until such time that all criteria are met.

Beginning in June 2016, subsequent to the U.S. Food and Drug Administration ("FDA") approval of Ocaliva® (obeticholic acid or "OCA") for the treatment of PBC, the Company sells Ocaliva in the United States principally to a limited number of specialty pharmacies which dispense the product directly to patients. The specialty pharmacies are referred to as the Company's customers.

The Company provides the right of return to its customers for unopened product for a limited time before and after its expiration date. Given the Company's limited sales history for Ocaliva and the inherent uncertainties in estimating product returns, the Company has determined that the shipments of Ocaliva made to its customers thus far do not meet the criteria for revenue recognition at the time of shipment. Accordingly, the Company recognizes revenue when the product is sold through by its customers, provided all other revenue recognition criteria are met. The Company invoices its customers upon shipment of Ocaliva to them and records accounts receivable, with a corresponding liability for deferred revenue equal to the gross invoice price. The Company then recognizes revenue when Ocaliva is sold through as specialty pharmacies dispense product directly to the patients.

The Company recognized net sales of Ocaliva for the three and nine months ended September 30, 2016 of $4.7 million and $4.8 million, respectively. The Company also recorded $2.2 million in deferred revenues recorded in short-term portion of deferred revenue on its balance sheet, which represents product shipped to distributors, but not sold through as of September 30, 2016.

The Company has written contracts with each of its customers and delivery occurs when the customer receives Ocaliva. The Company evaluates the creditworthiness of each of its customers to determine whether collection is reasonably assured. In order to conclude that the price is fixed and determinable, the Company must be able to (i) calculate its gross product revenues from the sales to its customers and (ii) reasonably estimate its net product revenues. The Company calculates gross product revenues based on the wholesale acquisition cost that the Company charges its customers for Ocaliva. The Company estimates its net product revenues by deducting from its gross product revenues (i) trade allowances, such as invoice discounts for prompt payment and customer fees, (ii) estimated government rebates and discounts related to Medicare, Medicaid and other government programs, and (iii) estimated costs of incentives offered to certain indirect customers including patients.

Trade Allowances

The Company provides invoice discounts on Ocaliva sales to certain of its customers for prompt payment and records these discounts as a reduction to gross product revenues. These discounts are based on contractual terms.

Rebates and Discounts

The Company contracts with Centers for Medicare & Medicaid Services (“CMS”) and other government agencies to make Ocaliva available to eligible patients. As a result, the Company estimates any rebates and discounts and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company’s estimates of rebates and discounts are based on the government mandated discounts, which are statutorily-defined and applicable to these government funded programs. These estimates are recorded in accrued liabilities on the condensed consolidated balance sheet.

Other Incentives

Other incentives that the Company offers to indirect customers include co-pay assistance cards provided by the Company for PBC patients whom reside in states that permit co-pay assistance programs. The Company’s co-pay

assistance program is intended to reduce each participating patient's portion of the financial responsibility for Ocaliva purchase price to a specified dollar amount. The Company estimates each period the amount of co-pay assistance provided to eligible patients based on the terms of the program when product is dispensed by the specialty pharmacies to the patients. These estimates are based on redemption information provided by third party claims processing organizations and are recorded in accrued liabilities on the condensed consolidated balance sheet.

Convertible Senior Notes

The Company's 3.25% convertible senior notes due 2023 (the "Convertible Notes") are accounted for in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 470, formerly FSP APB 14-1, Accounting for Convertible Debt Instruments That May be Settled in Cash upon Conversion (Including Partial Cash Settlement). ASC Subtopic 470-20 requires the issuer of convertible debt that may be settled in shares or cash upon conversion at the issuer's option, such as these notes, to account for the liability (debt) and equity (conversion option) components separately. The value assigned to the debt component is the estimated fair value, as of the issuance date, of a similar debt instrument without the conversion option. The amount of the equity component (and resulting debt discount) is calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument. The resulting debt discount is amortized as additional non-cash interest expense over the expected life of the notes utilizing the effective interest method. Although ASC 470 has no impact on the Company's actual past or future cash flows, it requires the Company to record non-cash interest expense as the debt discount is amortized. For additional information, see Note 6 – Long-Term Debt.

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 OCA as a therapeutic for the treatment of PBC, and NASH in Japan and China (excluding Taiwan). Under the terms of the license agreement, the Company received an up-front payment from Sumitomo Dainippon of $15.0 million and may be eligible to receive additional milestone payments of up to an aggregate of approximately $30.0 million in development milestones based on the initiation or completion of clinical trials, $70.0 million in regulatory approval milestones and $200.0 million in sales milestones. The regulatory approval milestones include $15.0 million for receiving marketing approval of OCA for NASH in Japan, $10.0 million for receiving marketing approval of OCA for NASH in China, and $5.0 million for receiving marketing approval of OCA for PBC in the United States, which was achieved upon the FDA approval of Ocaliva for the treatment of PBC in May 2016. As of September 30, 2016, the Company had achieved $6.3 million of the development milestones under its collaboration agreement with Sumitomo Dainippon. The sales milestones are based on aggregate sales amounts of OCA in the Sumitomo Dainippon territory and include $5.0 million for achieving net sales of $50.0 million, $10.0 million for achieving net sales of $100.0 million, $20.0 million for achieving net sales of $200.0 million, $40.0 million for achieving net sales of $400.0 million and $120.0 million for achieving net sales of $1.2 billion. The Company has determined that each potential future development, regulatory and sales milestone is substantive. In May 2014, Sumitomo Dainippon exercised its option under the license agreement to add Korea as part of its licensed territories and paid the Company a $1.0 million up-front fee. Sumitomo Dainippon has the option to add several other

Asian countries to its territory to pursue OCA for additional indications. Sumitomo Dainippon will be responsible for the costs of developing and commercializing OCA in its territories. Sumitomo Dainippon is also required to make royalty payments ranging from the tens to the twenties in percent based on net sales of OCA products in the Sumitomo Dainippon territory.

The Company evaluated the license agreement with Sumitomo Dainippon and determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under this license include an exclusive license to its technology, technical and scientific support to the development plan and participation on a joint steering committee. The Company determined that these performance obligations represent a single unit of accounting, since, initially, the license does not have stand-alone value to Sumitomo Dainippon without the Company's technical expertise and steering committee participation during the development of OCA. This development period is currently estimated as continuing through June 2020 and, as such, the up-front payment and payments made in respect of the Korea option are being recognized ratably over this period. During the three months ended September 30, 2016 and 2015, the Company recorded licensing revenue of approximately $0.4 million, respectively, and during the nine months ended September 30, 2016 and 2015, the Company recorded revenue of approximately $6.3 million and $2.3 million, respectively.

Leases

In January 2016, Intercept Pharma Europe Ltd. ("IPEL"), a wholly owned subsidiary of the Company, entered into an underlease with Performing Right Society, Ltd., for additional office space in the King's Cross area of London, United Kingdom. The Company is the guarantor to the underlease. The underlease provides IPEL with an additional 8,549 square feet of space. The lease term is anticipated to end in May 2024. The annual rent is approximately £726,665, payable quarterly. IPEL is also required to pay value added tax ("VAT") on the rent. IPEL will be responsible for a portion of the insurance, certain service charges and taxes for the building based on the floor area rented by them. As security for the underlease, IPEL has provided the landlord with a rent deposit in an amount equal to twelve months' rent, plus applicable VAT. The underlease is subject to an "upwards only" open market rent review of the market rent with review to take place in June 2019.

In February 2016, the Company entered into a sublease with Restoration Hardware, Inc. for additional office space in New York City. The sublease provides the Company with an additional 10,785 square feet of space. The lease term is anticipated to end in February 2021. The annual rent is approximately $1.0 million payable monthly. The Company is also responsible for its proportionate share of increases in operating expenses beginning January 2017 as well as its proportionate share of increases in real estate taxes over the average of the 2015/2016 and 2016/2017 fiscal years. As security for the sublease, the Company delivered a letter of credit in the amount of approximately $0.3 million in favor of the sublandlord.

On July 19, 2016, the Company entered into an amendment to its lease agreement with Irvine Eastgate Office II LLC for additional office space in San Diego, California. The amendment provides the Company with an additional 11,177 square feet of space. The lease term is anticipated to end in September 2019. The rent for the first year will be approximately $254,832 and will gradually increase every twelve months throughout the lease term for the additional space. 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. The landlord provided the Company with an allowance of approximately $22,354 for improvements to the office space. Pursuant to the terms of the amendment, the Company

provided the landlord with an additional letter of credit for $26,679.

Security for these leases is included on the condensed consolidated balance sheets in “Security Deposits.”

Commercial Supply Agreement

On August 12, 2016, IPEL and PharmaZell GMBH (“PharmaZell”), entered into a commercial manufacturing and supply agreement. Pursuant to the agreement, PharmaZell has agreed to manufacture and supply to IPEL and IPEL has agreed to purchase from PharmaZell a certain percentage of IPEL’s commercial requirements of active pharmaceutical ingredient (“API”) for use in Ocaliva. In addition, subject to certain regulatory events, IPEL has agreed to purchase a specified minimum quantity of API for delivery in 2017 and 2018. Subject to IPEL’s purchase obligations, IPEL has the right to enter into arrangements with one or more alternate sources for the commercial supply of API. The agreement provides for pricing for API structured on a tiered basis, with the price reduced as the volume of API ordered increases. The agreement has an initial term that runs through December 31, 2020, and is subject to two-year automatic renewal terms, unless either party provides notice of non-renewal at least 12 months prior to the end of the initial term or then-current renewal term. IPEL may terminate the agreement immediately with written notice upon the occurrence of certain regulatory events, or PharmaZell’s failure to meet certain quality standards, applicable laws or specified delivery obligations. Each party also has the right to terminate the agreement immediately upon written notice for other customary reasons such as material breach and bankruptcy. The agreement contains provisions relating to compliance by PharmaZell with current Good Manufacturing Practices and applicable laws, indemnification, confidentiality, intellectual property, dispute resolution and other customary matters for an agreement of this kind. Certain provisions of the agreement are subject to a quality agreement previously entered into by the parties. The Company has agreed to guarantee IPEL’s financial obligations under the agreement.

4. Financial Instruments

Financial instruments that potentially subject the Company to concentrations of credit risk consist of marketable investment securities. The Company's portfolio of marketable investment securities is subject to concentration limits set within the Company's investment policy that help the Company believes will limit its credit exposure.

The following table summarizes the Company’s cash, cash equivalents and investments as of September 30, 2016 and December 31, 2015:

	As of September 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$105,219	$ -	$ (3)	$105,216
Investment securities:				
U.S. government and agency securities	32,323	3	(4)	32,322
Commercial paper	70,074	-	(142)	69,932
Corporate debt securities	573,331	69	(911)	572,489
Total investments	675,728	72	(1,057)	674,743
Total cash, cash equivalents and investments	$780,947	$ 72	$ (1,060)	$779,959

	As of December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$32,742	$ -	$ -	$32,742
Investment securities:				
Commercial paper	1,993	-	(3)	1,990
U.S. government and agency securities	65,854	1	(182)	65,673
Corporate debt securities	529,368	2	(1,720)	527,650
Total investments	597,215	3	(1,905)	595,313
Total cash, cash equivalents and investments	$629,957	$ 3	$ (1,905)	$628,055

As of September 30, 2016, there were no marketable securities in a continuous unrealized loss position for more than twelve months.

5. 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:

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

- Level 2 - 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 3 - 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.

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

The Company's cash deposits and money market funds are classified within Level 1 of the fair value hierarchy because they are valued using bank balances or quoted market prices. Investments are classified as Level 2 instruments based on market pricing or other observable inputs. None of the Company's investments are classified within Level 3 of the fair value hierarchy.

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

		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
	(In thousands)			
September 30, 2016				
Assets:				
Money market funds	$39,356	$ 39,356	$ -	$ -
Available for sale securities:				
U.S. government and agency securities	32,322	-	32,322	-
Commercial paper	69,932	-	69,932	$ -
Corporate debt securities	572,489	-	572,489	-
Total financial assets:	$714,099	$ 39,356	$ 674,743	$ -
December 31, 2015				
Assets:				
Money market funds	$4,826	$ 4,826	$ -	$ -
Available for sale securities:				
Commercial paper	1,990	-	1,990	-
Corporate debt securities	527,650	-	527,650	-
U.S. government and agency securities	65,673	-	65,673	-

Total financial assets	$600,139	$ 4,826	$ 595,313	$ -

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

	Fair Value as of	
	September 30, 2016	December 31, 2015
	(In thousands)	
Due in one year or less	$415,106	$ 343,758
Due after 1 year through 2 years	259,637	251,555
Total investments in debt securities	$674,743	$ 595,313

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

6. Long-Term Debt

Debt, net of discounts and deferred financing costs, consists of the following:

	September 30, 2016	December 31, 2015
	(In thousands)	
Long-term debt	$337,898	$ -
Less current portion	-	-
Long-term debt outstanding	$337,898	$ -

On July 6, 2016, the Company issued $460.0 million aggregate principal amount of the Convertible Notes. The Company received net proceeds of $447.7 million after deducting underwriting discounts and estimated offering expenses of approximately $12.3 million. The Company used approximately $38.4 million of the net proceeds from the offering to fund the payment of the cost of the capped call transactions that were entered into in connection with the issuance of the Convertible Notes.

The Convertible Notes are senior unsecured obligations of the Company. Interest is payable semi-annually on January 1 and July 1 of each year, beginning on January 1, 2017. The Convertible Notes mature on July 1, 2023, unless earlier repurchased, redeemed or converted. The Convertible Notes are convertible at the option of holders, under certain circumstances and during certain periods, into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. The initial conversion rate of the Convertible Notes is 5.0358 shares of the Company's common stock per $1,000 principal amount of Convertible Notes, which is equivalent to an initial conversion price of approximately $198.58 per share of the Company's common stock. The conversion rate is subject to adjustment upon the occurrence of certain events. The Company may redeem for cash all or part of the Convertible Notes, at its option, on or after July 6, 2021, under certain circumstances at a redemption price equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

The capped call transactions are expected generally to reduce the potential dilution upon conversion of the Convertible Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Convertible Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Convertible Notes. The cap price of the capped call transactions is initially $262.2725 per share, and is subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of the Company's common stock, as measured under the terms of the capped call transactions, exceeds the cap price of the capped call transactions, there would nevertheless be dilution

upon conversion of the Convertible Notes to the extent that such market price exceeds the cap price of the capped call transactions.

In accordance with ASC Subtopic 470-20, the Company used an effective interest rate of 8.4% to determine the liability component of the Convertible Notes. This resulted in the recognition of $334.6 million as the liability component of the Convertible Notes and the recognition of the residual $113.1 million as the debt discount with a corresponding increase to additional paid-in capital for the equity component of the Convertible Notes.

Interest expense was $7.1 million for the three and nine months ended September 30, 2016 related to the Convertible Notes. Accrued interest on the Convertible Notes was approximately $3.7 million as of September 30, 2016. The Company recorded debt issuance costs of $12.3 million, which are being amortized using the effective interest method. As of September 30, 2016, $12.0 million of debt issuance costs are recorded on the unaudited condensed consolidated balance sheet in Long-Term Debt, in accordance with ASU 2015-03. As of September 30, 2016, the Company had outstanding borrowings of $460.0 million related to the Convertible Notes.

7. Income Taxes

For the nine months ended September 30, 2016 and 2015, no income tax expense or benefit was recognized. The Company’s deferred tax assets are comprised primarily of net operating loss carryforwards (“NOLs”). The Company maintains a full valuation allowance on its deferred tax assets since it has not yet achieved sustained profitable operations. As a result, the Company has not recorded any income tax benefit since its inception.

As of September 30, 2016 and December 31, 2015, the Company had NOLs for U.S. federal income tax purposes of $507.7 million and $454.4 million, respectively, which expire between 2024 and 2036. The Company also has certain state and foreign NOLs in varying amounts depending on the different state and foreign tax laws. The U.S. federal NOLs include approximately $167.5 million and $151.0 million, respectively, of excess tax benefits related to stock-based payments that are not recognized as a deferred tax asset. The benefit of these deductions will be recognized through additional paid-in capital at the time the tax deduction results in a reduction of current taxes payable.

The Company's ability to utilize its NOLs may be limited under Section 382 of the Internal Revenue Code due to previous ownership changes. Although the Company believes that these ownership changes have not resulted in material limitations on its ability to use these NOLs, its ability to utilize these NOLs may be limited due to future ownership changes or for other reasons. Additionally, tax laws limit the time during which NOLs and certain other tax attributes may be utilized against future taxes. As a result, the Company may not be able to take full advantage of its carryforwards for federal, state, and foreign tax purposes.

8. Stockholder's Equity

Common Stock

As of September 30, 2016 and December 31, 2015, the Company had 45,000,000 and 35,000,000, respectively, authorized shares of common stock, $0.001 par value per share. At the 2016 annual meeting of stockholders held on July 19, 2016, the Company's stockholders approved an amendment to the Company's restated certificate of incorporation, as amended, to increase the number of authorized shares of common stock from 35,000,000 shares to 45,000,000 shares.

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

In April 2015, the Company completed a public offering of 1,330,865 shares of its common stock pursuant to a registration statement on Form S-3. After underwriting discounts and commissions and offering expenses, the Company received net proceeds of approximately $367.1 million.

Stock-Based Compensation

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

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

The following table summarizes stock option activity during the nine months ended September 30, 2016:

	Number of Options (In thousands)	Weighted Average Exercise Price
Outstanding, December 31, 2015	1,348	$ 108.49
Granted	465	$ 112.52
Exercised	(164)	$ 27.39
Expired	(4)	$ 138.48
Forfeited	(51)	$ 141.23
Outstanding, September 30, 2016	1,594	$ 116.87
Exercisable, September 30, 2016	749	$ 85.63

The following table summarizes the aggregate RSU and RSA activity during the nine months ended September 30, 2016:

	Number of Awards (In thousands)	Weighted Average Fair Value	Aggregate Intrinsic Value (In thousands)
Non-vested shares outstanding, December 31, 2015	193	$ 183.19	$ 28,849
Granted	292	$ 116.08	$ 48,060
Exercised	(73)	$ 159.10	$ (12,015)
Forfeited	(24)	$ 167.60	$ (3,950)
Non-vested shares outstanding, September 30, 2016	388	$ 138.22	$ 63,861

As of September 30, 2016, there was $47.1 million of unrecognized compensation expense related to unvested RSUs and RSAs, which is expected to be recognized over a weighted average period of 2.69 years.

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,	
	2016	2015	2016	2015
	(In thousands, except per share amounts)			
Historical net loss per share				
Numerator:				
Net loss attributable to common stockholders	$(88,815)	$(50,895)	$(292,789)	$(138,175)
Denominator:				
Weighted average shares used in calculating net loss per share - basic and diluted	24,738	24,215	24,614	23,472
Net loss per share:				
Basic and diluted	$(3.59)	$(2.10)	$(11.90)	$(5.89)

16

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(In thousands)			
Options	1,594	1,203	1,594	1,203
Restricted stock units	388	25	388	25
Total	1,982	1,228	1,982	1,228

10. Recent Accounting Pronouncements.

In February 2016, the FASB issued ASU 2016-02, *Leases* ("ASU 2016-2") which supersedes Topic 840, Leases. ASU 2016-02 requires lessees to recognize a right-of-use asset and a lease liability on their balance sheets for all the leases with terms greater than twelve months. Based on certain criteria, leases will be classified as either financing or operating, with classification affecting the pattern of expense recognition in the income statement. For leases with a term of twelve months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. If a lessee makes this election, it should recognize lease expense for such leases generally on a straight-line basis over the lease term. ASU 2016-2 is effective for fiscal years beginning after December 15, 2018, and interim periods within those years, with early adoption permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients primarily focused on leases that commenced before the effective date of Topic 842, including continuing to account for leases that commence before the effective date in accordance with previous guidance, unless the lease is modified. The Company is evaluating the impact of the adoption of the standard on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting,* which is intended to improve the accounting for share-based payment transactions as part of the FASB's simplification initiative. The ASU changes certain aspects of the accounting for share-based payment award transactions, including: (1) accounting for income taxes; (2) classification of excess tax benefits on the statement of cash flows; (3) forfeitures; (4) minimum statutory tax withholding requirements; and (5) classification of employee taxes paid on the statement of cash flows when an employer withholds shares for tax-withholding purposes. The ASU is effective for fiscal years beginning after December 15, 2016, and interim periods within those years for public business entities. The Company is evaluating the impact of the adoption of the standard on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"). ASU 2014-09 supersedes the revenue recognition requirements of FASB ASC Topic 605, *Revenue Recognition* and most industry-specific guidance throughout the ASC, resulting in the creation of FASB ASC Topic 606, *Revenue from Contracts with Customers*. ASU 2014-09 requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. This ASU provides alternative methods of adoption. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers, Deferral of the Effective Date* ("ASU 2015-14"). ASU 2015-14 defers the effective date of ASU 2014-09 by one year to December 15, 2017 for fiscal years, and interim periods within those years, beginning after that date and permits early adoption of the standard, but not before the original effective date for fiscal years beginning after December 15, 2016. In March 2016, the FASB issued ASU 2016-08, *Revenue from Contracts with Customers, Principal versus Agent Considerations* (Reporting Revenue Gross versus Net) ("ASU 2016-08") clarifying the implementation guidance on principal versus agent considerations. Specifically, an entity is required to determine whether the nature of a promise is to provide the specified good or service itself (that is, the entity is a principal) or to arrange for the good or service to be provided to the customer by the other party (that is, the entity is an agent). The determination influences the timing and amount of revenue recognition. In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing*, clarifying the implementation guidance on identifying performance obligations and licensing. Specifically, the amendments reduce the cost and complexity of identifying promised goods or services and improves the guidance for determining whether promises are separately identifiable. The amendments also provide implementation guidance on determining whether an entity's promise to grant a license provides a customer with either a right to use the entity's intellectual property (which is satisfied at a point in time) or a right to access the entity's intellectual property (which is satisfied over time). The effective date and transition requirements for ASU 2016-08 and ASU 2016-10 are the same as the effective date and transition requirements for ASU 2014-09. The Company is currently assessing the potential impact of adopting ASU 2014-09, ASU 2016-08 and ASU 2016-10 on its financial statements and related disclosures.

11. 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 alleged 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 claimed that the January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo.

On April 22, 2014, two individuals each moved to consolidate the cases and a lead plaintiff was subsequently appointed by the Court. On June 27, 2014, the lead plaintiff filed an amended complaint on behalf of the putative class as contemplated by the order of the Court. The lead plaintiff was seeking unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees. On August 14, 2014, the defendants filed a motion to dismiss the complaint. Oral arguments on the motion to dismiss were held on February 24, 2015. On March 4, 2015, the defendants' motion to dismiss was denied by the Court. The defendants answered the amended complaint on April 13, 2015. On July 15, 2015, the plaintiff moved for class certification and appointment of class representatives and class counsel. On September 14, 2015, the defendants opposed the plaintiff's class certification motion. The plaintiff filed its reply to the defendants' opposition on October 14, 2015, to which the defendants filed a sur-reply on November 10, 2015. Oral arguments on the class certification motion were held on January 20, 2016.

On May 2, 2016, the defendants reached an agreement with the lead plaintiff to seek Court approval of a proposed resolution. The plaintiffs moved for preliminary approval of the proposed settlement on May 5, 2016. On May 23, 2016, the Court entered an order preliminarily approving the settlement. The Court ordered that notice be provided to the class and preliminarily approved the proposed settlement, including the payment of $55.0 million, of which $10.0 million was agreed to be funded by the Company's insurers. The settlement was paid into escrow in June 2016, with distribution to the class to occur after the Court had finally approved the settlement and the plan of allocation of those proceeds. On September 8, 2016, the Court granted final approval of the settlement. The final judgment and order of the Court included a dismissal of the action with prejudice against all defendants. The defendants do not admit any liability as part of the settlement.

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, 2015 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 29, 2016. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Item 1.A. "Risk Factors" of our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases with high unmet medical need utilizing our proprietary bile acid chemistry. Our marketed product and clinical product candidates have the potential to treat orphan and more prevalent liver diseases for which, currently, there are limited therapeutic solutions.

Our lead product, obeticholic acid, or OCA, is a bile acid analog, a chemical substance that has a structure based on a naturally occurring human bile acid that selectively binds to and activates the farnesoid X receptor, or FXR. We believe OCA has broad liver protective properties and may effectively counter a variety of chronic insults to the liver that cause fibrosis, or scarring, which can eventually lead to cirrhosis, liver transplant and death.

OCA was approved in the United States in May 2016 for use in patients with primary biliary cholangitis, or PBC, under the brand name Ocaliva®. We commenced sales and marketing of Ocaliva shortly after receiving marketing approval in the United States, and Ocaliva is now available to patients primarily through our specialty pharmacy distributors. In October 2016, the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, adopted a positive opinion recommending the conditional marketing authorization of Ocaliva in PBC. Based on the CHMP's positive recommendation, the final decision of the European Commission on the conditional marketing authorization of Ocaliva in PBC is expected by the end of 2016. We have also filed for regulatory approval for OCA in PBC in Canada and plan to file for marketing authorization in other target markets.

OCA is also being developed to treat a variety of other non-viral progressive liver diseases such as nonalcoholic steatohepatitis, or NASH, primary sclerosing cholangitis, or PSC, and biliary atresia. We are currently evaluating our future development strategy for OCA in other indications, for our product candidate INT-767 and for our pre-clinical candidates.

OCA has been tested in five placebo-controlled clinical trials, including a Phase 3 clinical trial in patients with PBC and two Phase 2 clinical trials in patients with NASH or a precursor disease to NASH known as nonalcoholic fatty liver disease, or NAFLD. OCA met the primary efficacy endpoint in each of these trials with statistical significance. In addition, in October 2015, we announced results from a Phase 2 dose ranging trial of OCA in 200 patients with NASH in Japan conducted by our collaborator, Sumitomo Dainippon Pharma Co., Ltd., or Sumitomo Dainippon. The results of this trial were mixed and are described in more detail in the “Business” section of our Annual Report on Form 10-K for the period ended December 31, 2015. Sumitomo Dainippon has informed us that it is exploring the initiation of its registrational trials for OCA in NASH patients intended to support the registration of this indication in Japan. OCA has received orphan drug designation in the United States and the European Union for the treatment of PBC and PSC and breakthrough therapy designation from the U.S. Food and Drug Administration, or FDA, for the treatment of NASH patients with liver fibrosis.

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 late July 2014. We have an ongoing Phase 3 clinical trial in non-cirrhotic NASH patients with liver fibrosis, known as the REGENERATE trial. REGENERATE includes a pre-planned histology-based interim analysis after 72 weeks of treatment. We are targeting completion of enrollment of the cohort of patients needed for this analysis in the first half of 2017, with results from the interim analysis anticipated in 2019. However, based on our current projections for this trial, we will need to continue to increase our enrollment rate to meet this timetable. We also have an ongoing Phase 2 clinical trial, known as the CONTROL trial, to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. We completed enrollment of the targeted number of patients for our CONTROL trial in October 2016 and expect top-line results in 2017. We continue to work towards expanding our overall NASH development program with additional trials and studies.

In addition to PBC and NASH, we continue to invest in research of OCA for additional patient populations with other liver diseases, including Phase 2 trials for PSC and pediatric patients with biliary atresia, respectively. In September 2016, we completed enrollment of the targeted number of patients in our Phase 2 AESOP trial in PSC. We expect top-line results from the AESOP trial in 2017. We also have an ongoing Phase 1 trial in healthy volunteers for INT-767, a dual FXR and TGR5 agonist. We anticipate completing this Phase 1 trial for INT-767 by the end of 2016. Following analysis of the results, we plan to evaluate next steps for INT-767 in 2017.

Our current patents for OCA are scheduled to expire at various times through 2033. Our current plan is to commercialize OCA ourselves in the United States and Europe for the treatment of PBC, NASH and other indications primarily by targeting physicians who specialize in the treatment of liver and intestinal diseases, including both hepatologists and gastroenterologists. We own worldwide rights to OCA except for Japan, China and Korea, where we have exclusively licensed OCA to Sumitomo Dainippon along with an option to exclusively license OCA in certain other Asian countries. We own or have rights to various trademarks, copyrights and trade names used in our business, including Ocaliva.

Our net loss for the three months ended September 30, 2016 and 2015 was approximately $88.8 million and $50.9 million, respectively. Our net loss for the nine months ended September 30, 2016 and 2015 was $292.8 million and $138.2 million, respectively. As of September 30, 2016, we had an accumulated deficit of approximately $988.4 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations.

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 as we:

- continue to commercialize Ocaliva for PBC in the United States;
- seek regulatory approval for and prepare to commercially launch Ocaliva for PBC in other jurisdictions;
- develop and seek regulatory approval for OCA in NASH and other indications;
- add infrastructure and personnel in the United States and internationally to support our product development and commercialization efforts; and
- operate as a public company.

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 additional 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.

On July 6, 2016, we completed an underwritten public offering of $460.0 million in aggregate principal amount of 3.25% convertible senior notes due 2023, or Convertible Notes. After deducting the underwriting discount and estimated offering expenses of approximately $12.3 million, the net proceeds from the Convertible Notes offering were approximately $447.7 million. We used approximately $38.4 million of the net proceeds from the offering to fund the payment of the cost of the capped call transactions we entered into in connection with the issuance of the

Convertible Notes. We intend to use the remaining net proceeds from the offering together with our existing cash, cash equivalents and short-term investments, to fund the ongoing commercialization of Ocaliva in PBC in the United States; our preparation for and, subject to receipt of marketing approval, potential initiation of the commercial launch of Ocaliva in PBC in certain European countries as well as certain other target markets across the world; the continued clinical development of OCA in PBC, NASH and PSC; the advancement of our clinical program for INT-767; and continued advancement of other preclinical pipeline and research and development programs. We also intend to use the balance of the net proceeds from the offering, if any, for general corporate purposes, including selling, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property.

Our principal executive offices are in New York, New York. We also have administrative offices in San Diego, California and London, United Kingdom.

Financial Overview

Revenue

We commenced our commercial launch of Ocaliva for use in PBC in the United States in June 2016. In the future, we expect to generate revenue primarily through product sales for Ocaliva.

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. When the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time that all criteria are met.

During the three and nine months ended September 30, 2016, we recognized net sales of Ocaliva of $4.7 million and $4.8 million, respectively. Cost of goods sold during each of the three and nine months ended September 30, 2016 was only reflective of packaging and labeling costs incurred in the respective period, which was de minimis. We expect cost of goods sold to remain negligible until previously expensed supplies of OCA are sold. We also recorded $2.2 million in deferred revenues on our balance sheet, which represents product shipped to distributors, but not sold through as of the end of September 30, 2016.

We also recognize revenue 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 $300.0 million in additional payments for development, regulatory and commercial sales milestones for OCA in the licensed territories. As of September 30, 2016, we have achieved $6.3 million of the development and regulatory 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 $6.3 million and $2.3 million in license revenue for the nine months ended September 30, 2016 and 2015, respectively. For the nine months ended September 30, 2016, $1.3 million resulted from the amortization of the up-front payments under the collaboration agreement and $5.0 million resulted from the regulatory milestone achieved in the period. For the nine months ended September 30, 2015, $1.3 million resulted from the amortization of the up-front payments under the collaboration agreement and $1.0 million resulted from the development milestone achieved in the period. 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.

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. Beginning in the third quarter of 2016, as a result of the regulatory approval of Ocaliva for the treatment of PBC, we began to capitalize inventory costs associated with the manufacturing of OCA for commercial use. Our research and development expenses consist primarily of direct costs, personnel costs and indirect costs such as the following:

Direct costs:

- fees paid to consultants and clinical research organizations, or CROs, including in connection with our preclinical activities and clinical trials, and other related fees, such as fees 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-based compensation granted to personnel in research and development functions.

Indirect costs:

·rent and other facilities-related costs;

·product-related legal costs; and

·business travel and meeting costs.

We anticipate that our research and development expenses will be substantial 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.

	Nine Months Ended September 30,	
	2016	2015
	(In thousands)	
Direct research and development expense by program:		
OCA	$ 56,489	$ 35,710
Research and discovery initiatives	3,026	5,161
INT-767	4,294	4,028
Total direct research and development expense	63,809	44,899
Personnel costs (1)	50,234	33,051
Indirect research and development expense	8,549	5,797
Total research and development expense	$ 122,592	$ 83,747

(1) Personnel costs, include stock-based compensation expense associated with stock options, restricted stock units, or RSUs, and restricted stock awards, or RSAs, granted to employees and non-employees of $12.9 million and $13.0 million for the nine months ended September 30, 2016 and 2015, respectively.

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. 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. We may also face delays in the regulatory review process.

OCA

Prior to 2016, our research and development efforts were primarily focused on the development of OCA for PBC as well as the preparation and work required for our New Drug Application, or NDA, and Marketing Authorizing Application, or MAA, filings with the FDA and EMA and efforts incurred in working on the regulatory review process. Although we received accelerated approval by the FDA for Ocaliva for the treatment of PBC in May 2016 and a positive opinion of the CHMP recommending the conditional approval of Ocaliva in PBC in Europe, we are continuing our Phase 4 COBALT clinical outcomes confirmatory trial and are undergoing our regulatory approval process in Europe and other jurisdictions. We have also invested with third-party manufacturers for supply chain and product development of OCA to prepare for the PBC commercial launch in certain European countries and the continuation of our clinical program in NASH, and are working to secure additional manufacturers as part of our strategy to secure multiple approved suppliers of OCA in the future.

In addition, we are evaluating OCA in non-viral, progressive liver diseases other than PBC, particularly NASH, PSC and biliary atresia. We have the following trials underway as part of our OCA development program: our Phase 3 REGENERATE trial in non-cirrhotic NASH patients with liver fibrosis, the Phase 2 CONTROL trial to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients, the Phase 2 AESOP trial of OCA in patients with PSC and the Phase 2 CARE trial of OCA in patients with biliary atresia. We continue to work towards expanding our overall NASH development program with additional trials and studies. As a result, we expect that our expenditures in connection with our NASH, PSC and biliary atresia programs will be substantial in future periods.

INT-767 and INT-777

We intend to continue to develop INT-767 and INT-777 (a selective TGR5 agonist). We currently have an ongoing Phase 1 clinical trial of INT-767 in healthy volunteers that was initiated in November 2015, which we anticipate completing by the end of 2016. We also intend to conduct additional preclinical work on INT-777 to further characterize its therapeutic potential and to invest in product development in anticipation of further clinical trials.

Other than OCA, our product development programs are at early stages, and successful development of 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 to make determinations as to which programs to pursue and how much funding to allocate 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.

Selling, General and Administrative Expenses

Selling, 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 selling, general and administrative expenses include non-cash stock-based compensation expenses, expenses related to our Ocaliva commercialization activities and OCA pre-commercialization activities, facilities costs, accounting and legal services, information technology and other expenses of operating as a public company.

Our selling, general and administrative expenses have increased and will continue to increase due to the commercialization of Ocaliva for PBC in the United States, the potential commercialization of OCA in PBC internationally and development activities for OCA in indications other than PBC and other product candidates. We further plan on expanding our operations both in the United States and Europe, which will increase our selling, general and administration expenses. We believe that these activities will result in increased costs related to the hiring of significant additional personnel, increased fees for outside consultants, lawyers and accountants, and the addition of facilities. We have also incurred and will continue to incur increased costs to comply with corporate governance, internal controls, compliance and similar requirements applicable to public companies with expanding operations and biopharmaceutical companies seeking to commercialize product candidates.

Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for each of the three months ended September 30, 2016 and 2015, together with the changes in those items in dollars:

	Three Months Ended September 30,		Dollar Change
	2016	2015	
	(In thousands)		
Revenue:			
Product revenue, net	$ 4,732	$ -	$ 4,732
Licensing revenue	445	445	-
Total revenue	5,177	445	4,732
Operating expenses:			
Research and development	43,838	27,487	16,351
Selling, general and administrative	44,375	24,742	19,633
Total operating expenses	88,213	52,229	35,984
Operating loss	(83,036)	(51,784)	(31,252)
Other income (expense):			
Interest expense	(7,065)	-	(7,065)
Other income, net	1,286	889	397
	(5,779)	889	(6,668)
Net loss	$ (88,815)	$ (50,895)	$ (37,920)

Revenues

Product revenue, net was $4.7 million and $0 for the three months ended September 30, 2016 and 2015, respectively. We commenced our commercial launch in the United States for Ocaliva in PBC in June 2016. For the three months ended September 30, 2016 and 2015, licensing revenue was $0.4 million, which resulted from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon.

Research and Development Expenses

Research and development expenses were $43.8 million and $27.5 million for the three months ended September 30, 2016 and 2015, respectively, representing a net increase of $16.3 million. This net increase in research and development expense primarily reflects:

- net increase in OCA research and development activities of approximately $7.5 million to support our clinical operations; and
- additional personnel on our research and development team to manage the increased activities around our OCA program and research and discovery initiatives, resulting in approximately $7.2 million of increased compensation-related costs and approximately $1.6 million of indirect costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $44.4 million and $24.7 million in the three months ended September 30, 2016 and 2015, respectively. The $19.7 million net increase primarily reflects:

- additional personnel-related costs of approximately $11.6 million to support our commercial and international initiatives;
- increased expenses of approximately $8.1 million in market research, Ocaliva, commercialization costs, and pre-launch activities.

Interest Expense

Interest expense was $7.1 million and $0 for the three months ended September 30, 2016 and 2015, respectively due to the issuance of our Convertible Notes in July 2016.

Other Income, Net

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which increased compared to the prior year period as a result of increases in cash and investment balances primarily due to the net proceeds from the issuance of the Convertible Notes.

Income Taxes

For the three months ended September 30, 2016 and 2015, no income tax expense or benefit was recognized. Our deferred tax assets are comprised primarily of net operating loss carryforwards. We maintain a full valuation allowance on our deferred tax assets since we have not yet achieved sustained profitable operations. As a result, we have not recorded any income tax benefit since our inception.

Comparison of the Nine Months Ended September 30, 2016 and 2015

The following table summarizes our results of operations for each of the nine months ended September 30, 2016 and 2015, together with the changes in those items in dollars:

	Nine Months Ended September 30,		Dollar Change
	2016	2015	
	(In thousands)		
Revenue:			
Product revenue, net	$4,807	$-	$ 4,807
Licensing revenue	6,336	2,336	4,000
Total revenue	11,143	2,336	8,807
Operating expenses:			
Research and development	122,592	83,747	38,845
Selling, general and administrative	177,082	58,854	118,228
Total operating expenses	299,674	142,601	157,073
Operating loss	(288,531)	(140,265)	(148,266)
Other income (expense):			
Interest expense	(7,065)	-	(7,065)
Other income, net	2,807	2,090	717
	(4,258)	2,090	(6,348)
Net loss	$(292,789)	$(138,175)	$ (154,614)

Licensing and Product Revenue

Product revenue, net was $4.8 million and $0 for the nine months ended September 30, 2016 and 2015, respectively. We commenced our commercial launch of Ocaliva in PBC in the United States in June 2016. Licensing revenue was $6.3 million and $2.3 million for the nine months ended September 30, 2016 and 2015, respectively. For the nine months ended September 30, 2016, $1.3 million resulted from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon and $5.0 million resulted from a regulatory milestone achieved in the period. For the nine months ended September 30, 2015, $1.3 million resulted from the amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon and $1.0 million resulted from a development milestone achieved in the period.

Research and Development Expenses

Research and development expenses were $122.6 million and $83.7 million for the nine months ended September 30, 2016 and 2015, respectively, representing a net increase of $38.9 million. This net increase in research and development expense primarily reflects:

- increased expenses of approximately $18.6 million attributable to the expansion of OCA research and development; and
- additional personnel on our research and development team to manage the increased activities around our OCA program and research and discover initiatives, resulting in an increase of approximately $17.2 million in compensation-related costs and approximately $2.6 million of indirect costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $177.1 million and $58.9 million in the nine months ended September 30, 2016 and 2015, respectively. The $118.2 million net increase primarily reflects:

- a one-time expense of approximately $45.0 million attributable to the settlement of the purported securities class action lawsuit, which reflects a settlement amount of $55.0 million of which $10.0 million was paid by our insurance carriers;

- increased personnel-related costs of approximately $31.3 million to support our increased corporate initiatives and commercialization activities;
- increased expenses of approximately $21.4 million in market research and other pre-launch activities;
- increased expenses of approximately $12.0 million for corporate initiatives to prepare for commercialization and to support future growth; and
- increased operating costs such as facilities and technology-related expenses of approximately $5.9 million.

Interest Expense

Interest expense was $7.1 million and $0 for the nine months ended September 30, 2016 and 2015, respectively, due to the issuance of our Convertible Notes in July 2016.

Other Income, Net

Other income, net was primarily attributable to interest income earned on cash, cash equivalents and investment securities, which increased compared to the prior year period as a result of increases in cash and investment balances.

Income Taxes

For the nine months ended September 30, 2016 and 2015, no income tax expense or benefit was recognized. Our deferred tax assets are comprised primarily of net operating loss carryforwards. We maintain a full valuation allowance on our deferred tax assets since we have not yet achieved sustained profitable operations. As a result, we have not recorded any income tax benefit since our inception.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2016, we had an accumulated deficit of $988.4 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 selling, 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 approximately $1.4 billion (net of issuance costs of $46.0 million), including $29.7 million in net proceeds from our Series C financing in August 2012, $78.7 million in net proceeds from our initial public offering in October 2012, $61.2 million in net proceeds from our follow-on public offering in June 2013, $183.5 million in net proceeds from a follow-on public offering in April 2014, $191.6 million in net proceeds from a follow-on public offering in February 2015, $367.1 million in net proceeds from the follow-on offering in April 2015, $447.7 million in net proceeds from the issuance of the Convertible Notes and the receipt of $17.4 million in up-front payments and milestones under our licensing and collaboration agreements with Sumitomo Dainippon and Servier. As of September 30, 2016, we had cash, cash equivalents and investment securities of $780.0 million.

We commenced our commercial launch of Ocaliva for use in PBC in the United States in June 2016. In the future, we expect to generate revenue primarily through product sales for Ocaliva.

Cash Flows

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

	Nine Months Ended September 30,	
	2016	2015
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (252,979)	$ (97,214)
Investing activities	(86,309)	(414,289)
Financing activities	413,780	564,351

Operating Activities. The increase in our net cash used in operating activities of approximately $155.8 million during the nine months ended September 30, 2016 as compared to the same period last year was primarily a result of increased activities in our business requiring more capital. Net cash used in operating activities of $253.0 million during the nine months ended September 30, 2016 was primarily a result of our $292.8 million net loss, offset by the add-back of non-cash items of $36.3 million and a net increase in operating assets and liabilities of $3.5 million. Net cash used in operating activities of $97.2 million during the nine months ended September 30, 2015 was primarily a result of our $138.2 million net loss, offset by the add-back of non-cash items of $27.6 million and a net increase in operating assets and liabilities of $13.4 million.

Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2016 was $86.3 million as compared to net cash used in investing activities for the nine months ended September 30, 2015 of $414.3 million. This net decrease in cash used in investing activities of approximately $328.0 million is primarily attributed to an increase in sales of investment securities and a decrease in investment purchases.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2016 were $413.8 million compared to $564.4 million for the comparable period in 2015. This net decrease in cash provided by financing activities of approximately $150.6 million was primarily the result of more net funds received through the completion of the February 2015 and April 2015 offerings in the nine months ended September 30, 2015 as compared to the proceeds received through the Convertible Notes issued during the nine months ended September 30, 2016, partially offset by the payments for the capped call transaction as described below.

Convertible Senior Notes and Capped Call Transactions

On July 6, 2016, we completed an underwritten public offering of $460.0 million in aggregate principal amount of 3.25% convertible senior notes due 2023 or the Convertible Notes. After deducting the underwriting discounts and estimated offering expenses of approximately $12.3 million, the net proceeds from the Convertible Notes offering were approximately $447.7 million. In connection with the offering, we entered into an indenture, as supplemented by the First Supplemental Indenture relating to the Convertible Notes, or collectively the Indenture, with U.S. Bank National Association, a national banking association, as trustee governing the Convertible Notes. The Convertible Notes bear interest at a rate of 3.25% per annum, payable semi-annually on January 1 and July 1 of each year, beginning on January 1, 2017. The Convertible Notes mature on July 1, 2023, unless earlier repurchased, redeemed or converted. Holders may convert the Convertible Notes at their option at any time prior to the close of business on the business day immediately preceding January 1, 2023 only under the following circumstances: (1) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on September 30, 2016, if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (2) during the five business day period after any five consecutive trading day period, or the measurement period, in which the trading price (as defined in the Indenture) per $1,000 principal amount of Convertible Notes for each trading day of the measurement period

was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; (3) if we call any or all of the Convertible Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (4) upon the occurrence of specified corporate events. On or after January 1, 2023 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Convertible Notes at any time, regardless of the foregoing circumstances. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock (and cash in lieu of any fractional shares) or a combination of cash and shares of our common stock, at our election. The conversion rate will initially be 5.0358 shares of our common stock per $1,000 principal amount of Convertible Notes (equivalent to an initial conversion price of approximately $198.58 per share of common stock). The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will increase the conversion rate for a holder who elects to convert its Convertible Notes in connection with such a corporate event in certain circumstances.

We may not redeem the Convertible Notes prior to July 6, 2021. We may redeem for cash all or any portion of the Convertible Notes, at our option, on or after July 6, 2021, if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the Convertible Notes.

If we undergo a fundamental change, holders may require us to repurchase for cash all or any portion of their convertible notes at a fundamental change repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Convertible Notes are our senior unsecured obligations and rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the Convertible Notes; equal in right of payment to our future unsecured indebtedness that is not so subordinated; effectively junior in right of payment to our future secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally subordinated to all existing and future indebtedness and other liabilities (including trade payables) incurred by our subsidiaries.

The Indenture contains customary events of default with respect to the Convertible Notes, including that upon certain events of default occurring and continuing, the trustee by notice to us, or the holders of at least 25% in principal amount of the outstanding Convertible Notes by notice to us, may (subject to the provisions of the Indenture) declare 100% of the principal of and accrued and unpaid interest, if any, on all the Convertible Notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization involving us or a significant subsidiary, 100% of the principal of and accrued and unpaid interest on the Convertible Notes will automatically become due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately.

In connection with the pricing of the Convertible Notes, we entered into privately-negotiated capped call transactions with Royal Bank of Canada, or RBC, UBS AG, London Branch, or UBS, and Credit Suisse Capital LLC, or Credit Suisse. The aggregate cost of the capped call transactions entered into in connection with the pricing of the notes was approximately $33.4 million. We and RBC, UBS and Credit Suisse entered into additional capped call transactions on July 1, 2016 in connection with the underwriters' exercise of their over-allotment option in full at an aggregate cost of approximately $5.0 million. The capped call transactions are generally expected to reduce the potential dilution upon conversion of the Convertible Notes in the event that the market price per share of our common stock, as measured under the terms of the capped call transactions, is greater than the strike price of the capped call transactions, which initially corresponds to the conversion price of the Convertible Notes, and is subject to anti-dilution adjustments generally similar to those applicable to the conversion rate of the Convertible Notes. The cap price of the capped call transactions will initially be $262.27 per share, and is subject to certain adjustments under the terms of the capped call transactions. If, however, the market price per share of our common stock, as measured under the terms of the capped call transactions, exceeds the cap price of the capped call transactions, there would nevertheless be dilution upon conversion of the Convertible Notes to the extent that such market price exceeds the cap price of the capped call transactions.

Future Funding Requirements

To date, we have not generated significant product sales revenues. While we have commenced our commercial launch of Ocaliva for use in PBC in the United States in June 2016, we cannot predict the period, if any, in which material net cash inflows from sales of OCA or our other product candidates may commence. 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 our plans to further expand our operations in the United States, Europe and in certain other countries. 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. As part of our longer term strategy, we also anticipate incurring significant expenses in connection with our planned increase in our product development, scientific, commercial and administrative personnel and expansion of our infrastructure and abroad. We anticipate that we will need substantial additional funding in connection with our continuing operations.

As of September 30, 2016, we had $780.0 million in cash, cash equivalents and investment securities. We currently project adjusted operating expenses of $320.0 million to $340.0 million for the fiscal year ending December 31, 2016, excluding the $45.0 million net expense for the settlement of the purported securities class action lawsuit, stock-based compensation and other non-cash items. We previously projected adjusted operating expenses in the lower end of the range of $360.0 million to $400.0 million for the fiscal year ending December 31, 2016. The decrease from our previous projection is due to lower than expected clinical trial costs and lower expenses due to the delayed timing in raw material purchases to manufacture of OCA for research and development purposes. Adjusted operating expenses are planned to support the continued clinical development program of OCA for PBC, NASH and PSC, increased OCA manufacturing activities for research and development purposes, the continued development of INT-767 and other preclinical pipeline programs, as well as pre-commercialization and commercialization activities.

Adjusted operating expense is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP. Other than the $45.0 million net expense for the class action lawsuit settlement, which is a one-time expense, 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. See “Non-GAAP Financial Measures” for more information.

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 mid-2018 over which we expect our cash and cash equivalents to be sufficient to fund our operating expenses and capital expenditure requirements. However, we currently believe that our cash and cash equivalents will be sufficient for us to:

- continue the initial commercialization of Ocaliva for PBC in the United States;

- prepare for and, if we obtain marketing approval on a timely basis, initiate the commercial launch of Ocaliva in PBC in certain European countries as well as certain other target markets across the world, but not commercially launch Ocaliva in PBC in other countries across the world;

- continue and expand our clinical development programs for OCA in PBC, NASH and PSC, such as continuing, but not completing, our planned Phase 3 clinical program for OCA in NASH, including the REGENERATE trial, a potential Phase 3 program for OCA in PSC, and our confirmatory clinical outcomes trials of OCA in PBC including COBALT; and

- advance the continued development of INT-767, including the completion of the ongoing Phase 1 clinical trial, and our preclinical compounds, but not completing the clinical or preclinical development needed to obtain regulatory approval, for and commercialize INT-767 or our preclinical compounds.

Accordingly, we will continue to require substantial additional capital in connection with our continuing operations, including continuing our commercialization plans and our research and development activities and building our global infrastructure to support these activities.

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

- the rate of progress and cost of our continued commercialization activities for Ocaliva in PBC in the United States;

- the receipt of the final decision of the European Commission on the conditional marketing authorization of Ocaliva in PBC in the European Union based on the positive recommendation of the CHMP;

- the degree of effort and time needed to prepare for and initiate the commercial launches of Ocaliva in PBC outside of the United States if we receive marketing authorization;

- the progress, costs, results of and timing of our clinical development programs for OCA in PBC, NASH and other indications, such as the sufficiency of the REGENERATE trial to be accepted as the sole pivotal trial for marketing approval or the acceptability of a surrogate endpoint for accelerated approval of OCA for the treatment of NASH and the post-marketing trials such as COBALT that we are required to conduct as a condition to our marketing authorizations for Ocaliva in PBC;

- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;

- the expansion of our research and development activities and the product candidates that we pursue, including INT-767 which is in a Phase 1 trial in healthy volunteers, and our product candidates in preclinical development such as INT-777;

- the significant expansion of our operations, personnel and the size of our company and our need to continue to expand in the longer term;

- the costs associated with securing and establishing manufacturing capabilities and procuring the materials necessary for our product candidates;

- market acceptance of our product candidates, which may be affected by the reimbursement that our products receive from payors;

- 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;

- the effect of competing technological and market developments; and

- other cash needs that may arise as we continue to operate our business.

We have no committed external sources of funding. 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 February 29, 2016.

On July 6, 2016, we completed an underwritten public offering of $460.0 million in aggregate principal amount of 3.25% convertible senior notes due 2023. In connection with the pricing of the Convertible Notes, we entered into privately-negotiated capped call transactions with RBC, UBS and Credit Suisse. See "—Liquidity and Capital Resources—Convertible Senior Notes and Capped Call Transactions" above.

On July 19, 2016, we entered into an amendment to our lease agreement with Irvine Eastgate Office II LLC for additional office space in San Diego, California. The amendment provides us with an additional 11,177 square feet of space. The lease term is anticipated to end in September 2019. The rent for the first year will be approximately $254,832 and will gradually increase every twelve months throughout the lease term for the additional space. We will be responsible for a portion of the insurance, certain service charges and taxes for the building based on the floor area rented by us. The landlord provided us with an allowance of approximately $22,354 for improvements to the office space. Pursuant to the terms of the amendment, we provided the landlord with an additional letter of credit for $26,679.

On August 12, 2016, Intercept Pharma Europe Ltd., or IPEL, our wholly-owned subsidiary, and PharmaZell GMBH, or PharmaZell, entered into a commercial manufacturing and supply agreement. Pursuant to the agreement, PharmaZell has agreed to manufacture and supply to IPEL and IPEL has agreed to purchase from PharmaZell a certain percentage of IPEL's commercial requirements of active pharmaceutical ingredient, or API, for use in Ocaliva. In addition, subject to certain regulatory events, IPEL has agreed to purchase a specified minimum quantity of API for delivery in 2017 and 2018. Subject to IPEL's purchase obligations, IPEL has the right to enter into arrangements with one or more alternate sources for the commercial supply of API. The agreement provides for pricing for API structured on a tiered basis, with the price reduced as the volume of API ordered increases. The agreement has an initial term that runs from until December 31, 2020, and is subject to two-year automatic renewal terms, unless either party provides notice of non-renewal at least 12 months prior to the end of the initial term or then-current renewal term. IPEL may terminate the agreement immediately with written notice upon the occurrence of certain regulatory events, or PharmaZell's failure to meet certain quality standards, applicable laws or specified delivery obligations. Each party also has the right to terminate the agreement immediately upon written notice for other customary reasons such as material breach and bankruptcy. The agreement contains provisions relating to compliance by PharmaZell with current Good Manufacturing Practices and applicable laws, indemnification, confidentiality, intellectual property, dispute resolution and other customary matters for an agreement of this kind. Certain provisions of the agreement are subject to a quality agreement previously entered into by the parties. We have agreed to guarantee IPEL's financial obligations under the agreement.

Off-Balance Sheet Arrangements

As of September 30, 2016, 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 February 29, 2016.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our disclosure controls are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, are recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of September 30, 2016, 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 during the quarter ended September 30, 2016 identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

As a result of our initial commercialization in the quarter ended June 30, 2016, we implemented processes and internal controls to record product revenues, deferred revenues, cost of sales and inventory. The implementation of these processes resulted in changes to our internal controls over financial reporting, which we believe were material. Further, we plan to continue to evaluate and enhance the design and documentation of our internal control over financial reporting process related to the recording of product revenues, cost of sales and inventory to maintain effective controls over our financial reporting.

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 alleged 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 claimed that the January 9, 2014 announcement was misleading because it did not contain information regarding certain lipid abnormalities seen in the FLINT trial in OCA-treated patients compared to placebo.

On April 22, 2014, two individuals each moved to consolidate the cases and a lead plaintiff was subsequently appointed by the Court. On June 27, 2014, the lead plaintiff filed an amended complaint on behalf of the putative class as contemplated by the order of the Court. The lead plaintiff was seeking unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees. On August 14, 2014, the defendants filed a motion to dismiss the complaint. Oral arguments on the motion to dismiss were held on February 24, 2015. On March 4, 2015, the defendants' motion to dismiss was denied by the Court. The defendants answered the amended complaint on April 13, 2015. On July 15, 2015, the plaintiff moved for class certification and appointment of class representatives and class counsel. On September 14, 2015, the defendants opposed the plaintiff's class certification motion. The plaintiff filed its reply to the defendants' opposition on October 14, 2015, to which the defendants filed a sur-reply on November 10, 2015. Oral arguments on the class certification motion were held on January 20, 2016.

On May 2, 2016, the defendants reached an agreement with the lead plaintiff to seek Court approval of a proposed resolution. The plaintiffs moved for preliminary approval of the proposed settlement on May 5, 2016. On May 23, 2016, the Court entered an order preliminarily approving the settlement. The Court ordered that notice be provided to the class and preliminarily approved the proposed settlement, including the payment of $55.0 million, of which $10.0 million was agreed to be funded by our insurers. The settlement was paid into escrow in June 2016, with distribution to the class to occur after the Court had finally approved the settlement and the plan of allocation of those proceeds. On September 8, 2016, the Court granted final approval of the settlement. The final judgment and order of the Court included a dismissal of the action with prejudice against all defendants. The defendants do not admit any liability as part of the settlement.

Item 1A. Risk Factors.

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. Other than as discussed below, there have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2015, as updated and superseded by the risk factors contained in our Quarterly Report on Form 10-Q for the period ended June 30, 2016. The risk factors described below update and supersede the corresponding risk factors contained in our Quarterly Report on Form 10-Q for the period ended June 30, 2016. For a further discussion of our Risk Factors, refer to the "Risk Factors" discussion contained in such filings. The risks and uncertainties described below and in our other filings are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 1 of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to the Development and the Regulatory Review and Approval of Our Product Candidate

We cannot be certain if Ocaliva® (obeticholic acid or OCA) will receive full approval in the United States for Primary Biliary Cholangitis, or PBC, or that Ocaliva will be approved for PBC outside of the United States. Furthermore, OCA may fail to become approved for any other indication and we may not be able to successfully receive regulatory approval for any other product candidate. Without regulatory approval we will not be able to market and commercialize our product candidates.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, in the United States, the European Medicines Agency, or EMA, in Europe and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States or Europe until we receive approval of a New Drug Application, or NDA, from the FDA or a Marketing Authorization Application, or MAA, from the EMA, respectively. Currently, our ability to generate revenue related to product sales will depend on the successful marketing of Ocaliva for PBC and the development and regulatory approval of OCA for the treatment nonalcoholic steatohepatitis, or NASH, and our other product candidates.

Ocaliva is our only drug that has been approved for sale and it has only been approved in the United States for the treatment of PBC under the accelerated approval pathway. Accelerated approval was granted for OCA in PBC based on a reduction in alkaline phosphatase; however, an improvement in survival or disease-related symptoms has not been established. Continued approval of Ocaliva for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Our Phase 4 COBALT confirmatory outcomes trial may fail to show a clinical benefit for OCA in PBC or may not satisfy the requirements of the regulatory authorities for other reasons.

As part of the post-marketing requirements, we are discussing modifications to the COBALT trial to potentially include a broader cross-section of PBC patients with early, moderately advanced and advanced disease according to the so-called Rotterdam criteria. We have agreed to evaluate the safety and efficacy of Ocaliva in patients with moderate to severe hepatic impairment and as monotherapy in patients with PBC. Finally, we have also agreed to develop and characterize a lower dose formulation of Ocaliva to allow for once daily dosing in patients with moderate or advanced hepatic impairment.

In October 2016, the Committee for Medicinal Products for Human Use, or CHMP, of the EMA adopted a positive opinion recommending the conditional marketing authorization of Ocaliva in PBC. Based on the CHMP’s positive recommendation, the final decision of the European Commission on the conditional marketing authorization of Ocaliva in PBC is expected by the end of 2016, with planned commercial launches thereafter in certain European countries leading to initial revenues in 2017. The marketing authorization in the European Union, if granted, will be

conditioned on the completion of the COBALT trial and a trial evaluating the safety and efficacy of Ocaliva in patients with moderate to severe hepatic impairment.

We have filed for regulatory approval in Canada for OCA in PBC. We also plan to apply for marketing approval of Ocaliva for PBC in certain other markets across the world.

We currently have no other products approved for sale and we cannot guarantee that we will ever have additional marketable products. NDAs and MAAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA or an MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. Even after the submission of an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. In addition, on June 23, 2016, eligible members of the electorate in the United Kingdom decided by referendum to leave the European Union, or Brexit. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially change the regulatory regime applicable to our operations, including with respect to the approval of our product candidates.

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

We will also be required to finalize the negotiations and discussions on our product labels for the respective jurisdictions in which we seek regulatory approval. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications or uses for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Also, regulatory approval for any of our product candidates may be withdrawn. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country.

We will need to complete a number of clinical trials and other studies for the continued development of OCA in indications other than PBC. For example, we currently have ongoing our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis and our Phase 2 CONTROL trial to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. We also intend to conduct additional trials in NASH, such as a Phase 2 program in NASH patients with cirrhosis. In each of these cases, our ability to obtain the approvals necessary to commercialize our product candidates will depend on our ability to conduct and complete these additional trials as well as assemble various other data to complete our regulatory filings for OCA in the relevant indication or patient population.

There can be no assurance that we will be able to receive the approval of the European Commission for OCA in PBC based on the CHMP's positive opinion, marketing approval for OCA in PBC other jurisdictions outside of the United States or marketing approval for OCA in NASH or any other indication. We cannot predict whether our trials and studies as to NASH or any other indication or patient population will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or require us to conduct additional studies or trials. For example, while OCA received breakthrough therapy designation from the FDA in January 2015 for the treatment of NASH patients with liver fibrosis, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulators will ultimately agree to a surrogate endpoint for accelerated approval of OCA for the treatment of NASH. While the interim histological endpoint is similar to that in the Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health, our Phase 3 REGENERATE trial has different trial designs. For example, the REGENERATE trial includes the following interim co-primary endpoints which are intended to serve as the basis for seeking marketing approvals in the United States, Europe and other countries: (i) the proportion of OCA-treated patients relative to placebo achieving at least one stage of liver fibrosis improvement with no worsening NASH and (ii) the proportion of OCA-treated patients relative to placebo achieving NASH resolution with no worsening of liver fibrosis. The REGENERATE trial will also remain blinded after the interim analysis and continue to follow patients until the occurrence of a pre-specified number of adverse liver-related clinical events, including progression to cirrhosis, to confirm clinical benefit on a post-marketing basis

Furthermore, the Phase 2 dose ranging trial of OCA in 200 adult NASH patients in Japan conducted by our collaborator, Sumitomo Dainippon, did not meet its primary endpoint with statistical significance. In this trial, there was a dose dependent, although not statistically significant, increase in the percentage of OCA treated patients

compared to placebo who achieved the primary endpoint (p=0.053). In addition, no difference was seen in fibrosis improvement in the OCA groups compared to placebo. The baseline characteristics between the patients in the Japanese Phase 2 trial conducted by Sumitomo Dainippon were distinct in a number of ways from those of the Western patients included in the Phase 2b FLINT trial conducted by NIDDK. For example, differences were observed among the patient population at baseline in relation to gender mix and metabolic factors like weight, diabetes status, dyslipidemia and hypertension. While our REGENERATE trial was designed based on the results of the FLINT trial and is anticipated to enroll a predominantly Western NASH patient population, the results of the FLINT trial may not be replicated in our REGENERATE trial. Although Sumitomo Dainippon has informed us that it is exploring the initiation of its registrational trials for OCA in NASH patients intended to support the registration of this indication in Japan, the results may not be an improvement as compared to those from the Phase 2 trial on Japanese NASH patients and there is no assurance that Sumitomo Dainippon will initiate any registrational trials.

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

We are developing product candidates for the treatment of rare diseases or diseases for which there are no or limited therapies, such as PBC, NASH and primary sclerosing cholangitis, or PSC, and for some of which there is little clinical experience, and our development approach involves new endpoints and methodologies. As a result, there is increased risk that we will not be able to gain agreement with regulatory authorities regarding an acceptable development plan, the outcome of our clinical trials will not be favorable or that, even if favorable, regulatory authorities may not find the results of our clinical trials to be sufficient for marketing approval.

We are focused on developing therapeutics for the treatment of rare diseases and diseases for which there are no treatments. As a result, the design and conduct of clinical trials for these diseases and other indications we may pursue will be subject to increased risk.

The FDA generally requires two pivotal clinical trials to approve an NDA. Furthermore, for full approval of an NDA, the FDA requires a demonstration of efficacy based on a clinical benefit endpoint. Under Subpart H regulations, the FDA can grant accelerated approval based on a surrogate reasonably likely to predict clinical benefit. Even if results from our planned pivotal clinical trials for a specific indication are highly significant and we believe reasonably likely to predict clinical benefit, the FDA may not accept the results of such trials and grant accelerated approval of our product candidate for such indication.

Even if we receive accelerated approval for any of our product candidates, we may be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of the product candidate by demonstrating the correlation of biochemical therapeutic response in patients with a significant reduction in adverse clinical outcomes over time. If a confirmatory clinical outcomes trial is required, we may be required to have the trial be substantially underway at the time we submit an NDA. It is possible that our NDA submission for regulatory approval will not be accepted by the FDA for review or, even if it is accepted for review, that there may be delays in the FDA's review process and that the FDA may determine that our NDA does not merit the approval of the product candidate, in which case the FDA may require that we conduct and/or complete additional clinical trials and preclinical studies before it will reconsider our application for approval.

Following discussions with regulatory authorities, we initiated our COBALT clinical outcomes confirmatory trial in PBC in December 2014 prior to the approval of Ocaliva. We are currently discussing modifications to the COBALT trial to potentially include a broader cross-section of PBC patients with early, moderately advanced and advanced disease according to the so-called Rotterdam criteria. We have agreed to evaluate the safety and efficacy of Ocaliva in patients with moderate to severe hepatic impairment and as monotherapy in patients with PBC. We have agreed to similar requirements with the EMA as part of the potential conditional approval of Ocaliva in PBC in Europe. We may be required to conduct other post-marketing studies based on our regulatory interactions with other regulatory agencies across the world. There can be no assurance that our COBALT trial or other trials conducted as part of our post-marketing obligations will confirm that the surrogate endpoints used for accelerated approval will eventually show an adequate correlation with clinical outcomes. If any such trial fails to show such adequate correlation, we may not be able to maintain our previously granted marketing approval for Ocaliva in PBC.

We also expect that the marketing authorization we receive in the European Union for Ocaliva for the treatment of PBC, if granted, will be conditional on post-approval studies and not considered a full approval. Our ability to obtain and maintain conditional marketing authorization in the European Union will be limited to specific circumstances and subject to several conditions and obligations, if obtained at all, including the completion of one or more clinical outcome trials to confirm the clinical benefit of Ocaliva in PBC. Conditional marketing authorizations based on incomplete clinical data may be granted for a limited number of listed medicinal products for human use, including products designated as orphan medicinal products under European Union law, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, including with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data, may be specified in the conditional marketing authorization. Conditional

marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions.

Our ongoing Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis, incorporates interim co-primary surrogate endpoints that may serve as the basis for a supplemental NDA filing for accelerated approval in the United States and approval in Europe. Accelerated approval in the United States and conditional approval in the European Union for OCA in NASH are subject to similar risks as discussed above in relation to OCA for PBC. The primary endpoint in the Phase 2b FLINT trial of OCA in NASH patients was based on liver biopsy and was defined as an improvement of two or more points in the NAFLD activity score (a system of scoring the histopathological features in the liver), or NAS, with no worsening of liver fibrosis and the co-primary endpoints for our REGENERATE trial are: (i) the proportion of OCA-treated patients relative to placebo achieving at least one stage of liver fibrosis improvement with no worsening NASH and (ii) the proportion of OCA-treated patients relative to placebo achieving NASH resolution with no worsening of liver fibrosis. Currently, other biopharmaceutical companies are enrolling or have initiated trials in certain subpopulations of NASH patients based on different endpoints from those in the FLINT and REGENERATE trials. Although the FDA acknowledged at recent workshops the possibility of granting accelerated approval for NASH therapies using surrogate endpoints, with potential examples including histological improvement, using the NAS or another scoring system, histological resolution of NASH, or improvements in fibrosis in pre-cirrhotic patients with NASH, the FDA did not provide any formal regulatory guidance on approvable endpoints and may not accept a surrogate endpoint for OCA for the treatment of NASH.

It is possible that if we seek marketing approval of OCA for non-cirrhotic NASH patients with liver fibrosis based on the interim results of our REGENERATE trial, our NDA submission may not be accepted by the FDA for review or, even if accepted for review, there may be delays in the FDA’s review process and the FDA may determine that our NDA does not merit the approval of OCA for the treatment of non-cirrhotic NASH patients. The FDA may also require that we continue our REGENERATE trial until its full completion to assess potential benefits of OCA treatment on liver-related and other clinical outcomes. Our regulatory pathway for OCA for the treatment of NASH will depend upon our discussions with the FDA and EMA. As a result, we may face difficulty in designing an acceptable registration strategy around REGENERATE or any other trials in different subpopulations of NASH patients. In addition, since the design of the REGENERATE trial deviates from that of the FLINT trial, there is an increased risk that the results of the REGENERATE trial would differ from the FLINT results.

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

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

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We initiated our Phase 4 COBALT clinical outcomes confirmatory trial of OCA in PBC in December 2014, our Phase 2 AESOP trial of OCA in PSC in December 2014, our Phase 3 REGENERATE trial of OCA in NASH in September 2015, our Phase 2 CARE trial of OCA in biliary atresia in October 2015 and our Phase 2 CONTROL trial to assess the lipid metabolic effects of OCA and the effects of concomitant statin administration in NASH patients in December 2015. The results from these trials may not be available when we expect or we may be required to conduct additional clinical trials or preclinical studies not currently planned to receive approval for OCA as a treatment for the related indication. In addition, our clinical programs are subject to a number of variables and contingencies, such as the results of other trials, patient enrollments or regulatory interactions that may result in a change in timing. As such, we do not know whether any future trials or studies of our other product candidates will begin on time or will be completed on schedule, if at all.

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

- inability to obtain sufficient funds required for a clinical trial or lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials, which may occur at various times, including subsequent to the initiation of the clinical trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our product candidates;
- the delay in receiving results from or the failure to achieve the necessary results in other clinical trials;

- inability to obtain approval from institutional review boards, or IRBs, to conduct a clinical trial at their respective sites;
- severe or unexpected drug-related adverse effects experienced by patients or any determination that a clinical trial presents unacceptable health risks;
- a breach of the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates, including Sumitomo Dainippon and Servier or investigators leading clinical trials on our product candidates;
- inability to timely manufacture sufficient quantities of the product candidate required for a clinical trial;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our trial, the rarity of the disease or the characteristics of the population being studied, the risks of procedures that may be required as part of the trial, such as a liver biopsy, and competition from other clinical trial programs for the same indications as our product candidates; and
- inability to retain enrolled patients after a clinical trial is underway.

For example, our REGENERATE trial is a large and complex Phase 3 clinical trial in a disease without any approved therapies and involves serial liver biopsies. We continue to strive to complete enrollment of our interim analysis cohort within the first half of 2017; however, based on our current projections for this trial, we will need to continue to increase our enrollment rate to meet this timetable. While we continuously evaluate and implement a variety of options to maintain our timelines, there can be no assurance that we will be able to enroll a sufficient number of patients or complete the interim analysis or the trial on a timely basis

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

Clinical failure can occur at any stage of clinical development. The results of earlier clinical trials are not necessarily predictive of future results and any product candidate we, Sumitomo Dainippon, Servier or our potential future collaborators advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical trials and at other stages of clinical development, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. If OCA or our other product candidates are found to be unsafe or lack efficacy for any indication, we will not be able to obtain regulatory approval for them, and our prospects and business may be materially and adversely affected.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes or differences in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If we are unable to bring any of our current or future product candidates to market, or to acquire any marketed, previously approved products, our ability to create long-term stockholder value will be limited.

Although Ocaliva has received accelerated approval in the United States and has received the positive opinion of the CHMP recommending conditional approval for PBC, its full approval depends on the results of post-marketing

clinical trials, including the Phase 4 COBALT trial. We cannot assure you that these trials will demonstrate a correlation of biochemical therapeutic response in patients taking Ocaliva with a significant reduction in adverse clinical events over time.

In December 2014, we received comprehensive datasets from the FLINT trial, which met its primary endpoint with statistical significance. In October 2015, we announced that the Phase 2 dose ranging trial of OCA in the Sumitomo Dainippon Phase 2 trial did not meet its primary endpoint with statistical significance. In this trial, there was a dose dependent, although not statistically significant, increase in the percentage of OCA treated patients compared to placebo who achieved the primary endpoint (p=0.053). In addition, no difference was seen in fibrosis improvement in the OCA groups compared to placebo. The Phase 2 trial in NASH conducted in Japan by our collaborator Sumitomo Dainippon involved different doses of OCA being administered to the trial subjects than those utilized in FLINT. Furthermore, the baseline characteristics between the patients in the Japanese Phase 2 trial conducted by Sumitomo Dainippon were distinct in a number of ways from those of the Western patients included in FLINT. While our REGENERATE trial was designed based on the results of the FLINT trial and is anticipated to enroll a predominantly Western NASH patient population, the results of the FLINT trial may not be replicated in our REGENERATE trial. In addition, since the design of the REGENERATE trial deviates from that of the FLINT trial, there is an increased risk that the results of the REGENERATE trial would differ from the FLINT results. Even though OCA has been granted breakthrough therapy designation by the FDA, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulators will agree to a surrogate endpoint for accelerated approval of OCA for the treatment of NASH. As a result, it may take longer than anticipated to initiate and complete the Phase 3 REGENERATE trial or our Phase 3 program in NASH for other patient subpopulations.

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

OCA has been shown to be a potent agonist of the farnesoid X receptor, or FXR. With the exception of the endogenous human bile acid chenodeoxycholic acid, or CDCA, and cholic acid, there are no approved FXR agonists and the adverse effects from long-term exposure to this drug class are unknown. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed.

The most common side effects observed in clinical trials of OCA in PBC were pruritus, or itching, fatigue, headaches, nausea, constipation and diarrhea. In our Phase 2 PBC clinical trial of OCA in combination with ursodiol, approximately 8% of the patients enrolled in the 10 mg and 25 mg dose groups withdrew from the trial due to severe pruritus. At the 50 mg dose, approximately 25% of the patients withdrew from the trial due to severe pruritus. In our POISE trial, pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment and was observed in 38% of patients on placebo, 70% of patients in the 10 mg OCA group and 56% of patients in the OCA titration group (5 mg to 10 mg). Eight patients discontinued due to pruritus, of whom none were in the placebo group, seven (10%) patients were in the 10 mg OCA group and one (1%) patient was in the OCA titration group. Pruritus also has been observed in other clinical trials of OCA. Decreases in HDL cholesterol were also observed during treatment in the POISE trial. In our Phase 2 trials for OCA in PBC, a dose-response relationship was observed for the occurrence of liver-related adverse reactions, including jaundice, ascites and primary biliary cholangitis flare with dosages of OCA of 10 mg once daily to 50 mg once daily (up to 5-times the highest recommended dosage), as early as one month after starting treatment with OCA.

Ocaliva is contraindicated for patients with complete biliary obstruction. For patients with moderate or severe hepatic impairment, who represent approximately 3% of PBC patients, the U.S. label for Ocaliva in PBC includes an adjustment in the dosing regimen due to potential exposure levels in this population. For patients with HDL reductions and no response to Ocaliva after one year at the maximum tolerated dose, the U.S. label asks prescribing physicians to weigh the risks against the benefits of continuing treatment.

Based on information in the manuscript for the FLINT trial published in November 2014, pruritus occurred more frequently in the OCA treatment group than in the placebo treatment group (23% vs. 6%, $p < 0.001$) and at a higher grade (predominately moderate pruritus), but resulted in only one patient discontinuation in the OCA treatment group. In the FLINT trial, OCA treatment was associated with changes in serum lipid levels, including increases in total cholesterol and LDL cholesterol and a decrease in HDL cholesterol, that were observed within 12 weeks of initiating treatment, peaked and then decreased in magnitude while on treatment, and reversed further during the 24-week post-treatment period. As previously disclosed, these changes in cholesterol levels, along with achieving the pre-defined efficacy criteria, played a role in the decision of the FLINT data and safety monitoring board to terminate the treatment phase of FLINT, and the publication of the FLINT results has noted the need for further study of these changes. In December 2015, we initiated CONTROL, a Phase 2 trial characterizing the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. We completed enrollment of the targeted number of patients for our CONTROL trial in October 2016. There were two patient deaths in the FLINT trial, and neither death was considered related to OCA treatment.

Additional or unforeseen side effects from OCA or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. With the approval of Ocaliva in PBC, OCA will be used in an environment that is less rigorously controlled than in clinical studies. If new side effects are found, if known side effects are shown to be more severe than previously observed or if OCA is shown to have other unexpected characteristics, we may need to abandon our development of OCA for NASH, PSC, biliary atresia and other potential indications. Furthermore, our commercial efforts for Ocaliva in PBC may be materially and adversely affected.

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

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

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

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;

- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market; we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Breakthrough therapy designation for OCA may not lead to faster development or regulatory processes nor does it increase the likelihood that OCA will receive marketing approval for NASH.

If a drug is intended for the treatment of a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development, the FDA may grant a breakthrough therapy designation. Breakthrough therapy designation is intended to facilitate the development, and expedite the review of such drugs, but the breakthrough therapy designation does not assure any such qualification or ultimate marketing approval by the FDA.

In January 2015, we received breakthrough therapy designation for OCA in the treatment of NASH patients with fibrosis. However, there is no guarantee that the receipt of breakthrough therapy designation will result in a faster development process, review or approval for OCA in fibrotic NASH patients or increase the likelihood that OCA will be granted marketing approval for fibrotic NASH patients. Likewise, any future breakthrough therapy designation for any other potential indication of OCA neither guarantees a faster development process, review or approval nor improves the likelihood of the grant of marketing approval by FDA for any such potential indication of OCA compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw any breakthrough therapy designation at any time. We may seek a breakthrough therapy designation for other of our product candidates, but the FDA may not grant this status to any of our proposed product candidates.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates, if approved, which would cause our revenues to suffer.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same product for that time

period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. In addition, it is possible that orphan drug designation in Europe will not be maintained following approval if the EMA determines that the product does not satisfy the requisite criteria including demonstration of significant clinical benefit. In November 2015, the European Commission set forth a consultation document and a notice detailing proposed amendments to the rules governing orphan medicinal products which may make it more difficult to demonstrate significant clinical benefit at the time of marketing authorization. The result of this process may impact our ability to obtain or maintain orphan drug designation in Europe.

The failure to maintain orphan status may impact our ability to receive a premium price for OCA or our other products and may subject us to mandatory price discounts in Europe. In addition, our ability to launch in Europe may be delayed and we may lose other benefits such as tax exemptions for sales. As such, the loss of orphan drug status may have a negative effect on our ability to successfully commercialize our products, earn revenues and achieve profitability.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Even after an orphan drug is approved, the FDA and EMA can subsequently approve the later product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

If the FDA and EMA and other regulatory agencies do not approve the manufacturing facilities of our future contract manufacturers for commercial production on a timely basis or at all, we may not be able to commercialize any of our product candidates or commercialization of our product candidates could be delayed.

We do not intend to manufacture the pharmaceutical products that we plan to sell. We currently have agreements with a contract manufacturer for the production of the active pharmaceutical ingredients and the formulation of sufficient quantities of drug product for the COBALT clinical outcomes confirmatory trial of OCA in PBC and the long-term safety extension phase of the POISE trial for OCA in PBC, our Phase 3 NASH program for OCA, including the REGENERATE trial, and the certain other trials and preclinical studies that we plan to conduct prior to and after seeking regulatory approval. If our contract manufacturer should cease to provide services to us for any reason, we likely would experience delays in advancing our clinical trials while we identify and qualify one or more replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us.

We currently have a long-term supply agreement with PharmaZell GMBH for the manufacture of commercial supply for Ocaliva. While we have procured sufficient supplies for the commercial launch of Ocaliva in PBC, we may not be able to procure sufficient supplies of Ocaliva on a continued basis. We are also seeking to qualify one or more back-up suppliers for our active ingredients; however, we may not be able to enter into additional long-term commercial supply agreements for OCA with other third-party manufacturers. We do not have agreements for long-term supplies of any of our other product candidates. We currently obtain these supplies and services from our third-party contract manufacturers on a purchase order basis.

Additionally, the facilities used by any contract manufacturer to manufacture OCA or any of our other product candidates must be the subject of a satisfactory inspection before the FDA or the regulators in other jurisdictions approve the product candidate manufactured at that facility. We are completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and current good manufacturing practice requirements of any governmental agency whose jurisdiction to which we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates, including:

- the possibility that we are unable to enter into a manufacturing agreement with a third party to manufacture OCA or our product candidates;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or disruption of commercialization of our product candidates, cause us to incur higher costs, prevent us from commercializing our product candidates successfully or disrupt the supply of our products after commercial launch. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the government agencies that regulate our products.

Even if our product candidates receive regulatory approval, we will still be subject to strict regulatory requirements governing manufacturing and marketing of our products and, as a result, we could face future development and regulatory difficulties.

Our product candidates, if approved, will also be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and EMA requirements and requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMPs. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and EMA and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products for indications or uses for which they are not approved.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our collaborators to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us, Sumitomo Dainippon, Servier or our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

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

Recent Sales of Unregistered Securities

Set forth below is information regarding securities sold by us during the nine months ended September 30, 2016 that were not registered under the Securities Act of 1933, as amended, or Securities Act. Also included is the consideration, if any, received by us for the securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

Between January 1 and September 30, 2016, we did not issue or sell any shares on an unregistered basis.

Purchase of Equity Securities

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

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

SIGNATURES

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

INTERCEPT PHARMACEUTICALS, INC.

Date: November 9, 2016 By: /s/ Mark Pruzanski, M.D.
Mark Pruzanski
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2016 By: /s/ Sandip Kapadia
Sandip Kapadia
Chief Financial Officer
(Principal Financial Officer)

Exhibit Index

Exhibit Number	Description of Exhibit
3.1	Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K, filed July 22, 2016).
4.1	Indenture, dated as of July 6, 2016, by and between the Registrant and UBS Bank National Associate, a national banking association, as trustee (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K, filed July 6, 2016).
4.2	First Supplemental Indenture (including the Form of Note), dated as of July 6, 2016, by and between the Registrant and U.S. Bank National Association, a national banking association, as trustee (incorporated by reference to Exhibit 4.2 to the Registrant's current report on Form 8-K, filed July 6, 2016).
10.1	Call Options Confirmation between the Registrant and Royal Bank of Canada, dated as of June 30, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K, filed July 6, 2016).
10.2	Additional Call Option Confirmation between the Registrant and Royal Bank of Canada, dated as of July 1, 2016 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K, filed July 6, 2016).
10.3	Call Option Confirmation between the Registrant and UBS AG, London Branch, dated as of June 30, 2016 (incorporated by reference to Exhibit 10.3 to the Registrant's current report on Form 8-K, filed July 6, 2016).
10.4	Additional Call Option Confirmation between the Registrant and UBS AG, London Branch, dated as of July 1, 2016 (incorporated by reference to Exhibit 10.4 to the Registrant's current report on Form 8-K, filed July 6, 2016).
10.5	Call Option Confirmation between the Registrant and Credit Suisse Capital LLC, dated as of June 30, 2016 (incorporated by reference to Exhibit 10.5 to the Registrant's current report on Form 8-K, filed July 6, 2016).
10.6	Additional Call Option Confirmation between the Registrant and Credit Suisse Capital LLC, dated as of July 1, 2016 (incorporated by reference to Exhibit 10.6 to the Registrant's current report on Form 8-K, filed July 6, 2016).
10.7	Amended Lease Agreement between The Irvine Company LLC and the Registrant, dated July 19, 2016.
10.8	Commercial Manufacturing and Supply Agreement by and between the Registrant and PharmaZell GMBH, dated August 12, 2016.*

31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at September 30, 2016 (unaudited) and December 31, 2015 (unaudited), (ii) Condensed Consolidated Statements of Operations for the three and nine month periods ended September 30, 2016 and 2015 (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine month periods ended September 30, 2016 and 2015, (iv) Condensed Consolidated Statements of Cash Flows for the nine month periods ended September 30, 2016 and 2015 (unaudited) and (v) Notes to Condensed Consolidated Financial Statements (unaudited).

* Confidential treatment has been requested from the Securities and Exchange Commission as to certain portions.