UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	
(Address of Principal Executive Offices)	**10011 (Zip Code)**

(646) 747-1000
(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

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

Intercept Pharmaceuticals, Inc.

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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,” “would,” “could,” “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.

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	Weighted Average Exercise Price
	(In thousands)	
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	Weighted Average Fair Value	Aggregate Intrinsic Value
	(In thousands)		(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)

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.

SECOND AMENDMENT TO LEASE

THIS SECOND AMENDMENT TO LEASE (the "**Amendment**") is made and entered into as of July 19, 2016, by and between **IRVINE EASTGATE OFFICE II LLC,** a Delaware limited liability company ("**Landlord**"), and **INTERCEPT PHARMACEUTICALS, INC.,** a Delaware corporation ("**Tenant**").

RECITALS

A. Landlord (as successor in interest to The Irvine Company LLC, a Delaware limited liability company) and Tenant are parties to that certain lease dated May 1, 2014, which lease has been previously amended by First Amendment to Lease dated December 19, 2014 (collectively, the "**Lease**"). Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately **47,000** rentable square feet (the "**Original Premises**") described as Suite No. 100 on the 1st floor of the building located at 4760 Eastgate Mall, San Diego, California (the "**4760 Building**").

B. Tenant has requested that additional space containing approximately 11,177 rentable square feet described as Suite No. 250 on the 2nd floor of the building located at 4780 Eastgate Mall, San Diego, California (the "**4780 Building**") shown on **Exhibit A** hereto (the "**Expansion Space**") be added to the Original Premises and that the Lease be appropriately amended and Landlord is willing to do the same on the following terms and conditions.

NOW, THEREFORE, in consideration of the above recitals which by this reference are incorporated herein, the mutual covenants and conditions contained herein and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree as follows:

I. **Expansion and Effective Date.**

A. The Term for the Expansion Space shall commence ("**Expansion Effective Date**") on the earlier of (a) the date the Expansion Space is deemed ready for occupancy pursuant to Section I.B below, or (b) the date Tenant commences its business activities within the Expansion Space, and shall expire upon the Expiration Date (i.e., September 30, 2019). The Expansion Effective Date is estimated to be August 1, 2016 ("**Estimated Expansion Effective Date**"). Promptly following request by Landlord, the parties shall memorialize on a form provided by Landlord (the "**Expansion Effective Date Memorandum**") the actual Expansion Effective Date; should Tenant fail to execute and return the Expansion Effective Date Memorandum to Landlord within 10 business days (or provide specific written objections thereto within that period), then Landlord's determination of the Expansion Effective Date as set forth in the Expansion Effective Date Memorandum shall be conclusive. Effective as of the Expansion Effective Date, the Premises, as defined in the Lease, shall be increased from 47,000 rentable square feet to **58,177** rentable square feet by the addition of the Expansion Space.

B. Delay in Possession. If Landlord, for any reason whatsoever, cannot deliver possession of Expansion Space to Tenant on or before the Expansion Effective Date set forth in Section I.A above, this Amendment shall not be void or voidable nor shall Landlord be liable to Tenant for any resulting loss or damage. However, Tenant shall not be liable for any rent for the Expansion Space and the Expansion Effective Date shall not occur until Landlord delivers possession of the Expansion Space and the Expansion Space is in fact ready for occupancy as defined below, except that if Landlord's failure to so deliver possession is attributable to any action or inaction by Tenant (including without limitation any Tenant Delay described in the Work Letter, if any, attached to this Amendment), then the Expansion Space shall be deemed ready for occupancy, and Landlord shall be entitled to full performance by Tenant (including the payment of rent), as of the date Landlord would have been able to deliver the Expansion Space to Tenant but for Tenant's delay(s). Subject to the foregoing, the Expansion Space shall be deemed ready for occupancy if and when Landlord, to the extent applicable, (a) has put into operation all building services essential for the use of the Expansion Space by Tenant, (b) has provided reasonable access to the Expansion Space for Tenant so that it may be used without unnecessary interference, (c) has substantially completed all the work required to be done by Landlord in this Amendment, and (d) has obtained requisite governmental approvals to Tenant's occupancy.

II. **Basic Rent.** In addition to Tenant's obligation to pay Basic Rent for the Original Premises, Tenant shall pay Landlord Basic Rent for the Expansion Space as follows:

Months of Term or Period	Monthly Rate Per Square Foot	Monthly Basic Rent
8/1/16 to 7/31/17	$ 1.90	$ 21,236.00
8/1/17 to 7/31/18	$ 1.99	$ 22,242.00
8/1/18 to 7/31/19	$ 2.07	$ 23,136.00
8/1/19 to 9/30/19	$ 2.17	$ 24,254.00

All such Basic Rent shall be payable by Tenant in accordance with the terms of the Lease.

Landlord and Tenant acknowledge that the foregoing schedule is based on the assumption that the Expansion Effective Date is the Estimated Expansion Effective Date. If the Expansion Effective Date is other than the Estimated Expansion Effective Date, the schedule set forth above with respect to the payment of any installment(s) of Basic Rent for the Expansion Space shall be appropriately adjusted on a per diem basis to reflect the actual Expansion Effective Date, and the actual Expansion Effective Date shall be set forth the Expansion Effective Date Memorandum to be prepared by Landlord. However, the effective date of any increases or decreases in the Basic Rent rate shall not be postponed as a result of an adjustment of the Expansion Effective Date as provided above.

III. **Project Costs and Property Taxes**. For the period commencing on the Expansion Effective Date and ending on the Expiration Date, Tenant shall be obligated to pay Tenant's Share of Operating Expenses accruing in connection with the Expansion Space in accordance with the terms of the Lease. "**Tenant's Share**" as used in this Section III shall mean (i) the proportion of the Operating Expenses of the 4780 Building determined by the fraction of the rentable square footage of the Expansion Space (11,177) as compared to the total rentable square footage of the 4780 Building (47,000) which fraction shall equal 23.781%, plus (ii) that portion of any Operating Expenses (except any Operating Expenses relating to the 4780 Building calculated as part of clause (i) of this definition) determined by multiplying the cost of such item by a fraction, the numerator of which is the rentable square footage of the Expansion Space (11,177) and the denominator of which is the total rentable square footage, as determined from time to time by Landlord, of all or some of the buildings in the Project, for expenses determined by Landlord in good faith to benefit or relate substantially to all or some of the buildings in the Project rather than any specific building.

IV. **Additional Letter of Credit**. Landlord is currently holding a Letter of Credit in the amount of $614,548.33. Concurrently with Tenant's delivery of this Amendment, in lieu of a cash Security Deposit, Tenant may deliver to Landlord, an additional letter of credit in the amount of $26,679.00 (the "**Additional Letter of Credit**"), which Additional Letter of Credit shall be in form and with the substance of **Exhibit B** attached hereto. The Additional Letter of Credit shall be issued by a financial institution acceptable to Landlord with a branch in San Diego County, California, at which draws on the Additional Letter of Credit will be accepted. The Additional Letter of Credit shall provide for automatic yearly renewals throughout the Term for the Expansion Space, and shall have an outside expiration date (if any) that is not earlier than 30 days after the expiration of the Term for the Expansion Space. In the event the Additional Letter of Credit is not continuously renewed through the period set forth above, or upon any breach under the Lease by Tenant, including specifically Tenant's failure to pay Rent or to abide by its obligations under Sections 7.1 and 15.3 of the Lease, Landlord shall be entitled to draw upon said Additional Letter of Credit by the issuance of Landlord's sole written demand to the issuing financial institution. Any such draw shall be without waiver of any rights Landlord may have under the Lease or at law or in equity as a result of any default by Tenant.

V. **Improvements**.

A. Condition of Expansion Space. Tenant has inspected the Expansion Space and agrees to accept the same "as is" without any agreements, representations, understandings or obligations on the part of Landlord to perform any alterations, repairs or improvements, except as may be expressly provided otherwise in this Amendment.

B. Tenant Improvements. Landlord shall cause its contractor to make such improvements to the Expansion Space as may be specified by Tenant and approved by Landlord not later than July 31, 2016 ("**Tenant Improvements**"). All such improvements shall be set forth at one time by Tenant as part of a single plan, it being understood that Landlord shall not be required to undertake multiple jobs. All materials and finishes utilized in completing the Tenant Improvements shall be Landlord's building standard. Should Landlord submit any matter to Tenant for approval, Tenant shall approve or reasonably disapprove same (with reasons specified) within 5 business days.

Landlord's total contribution for the Tenant Improvements shall not exceed $22,354.00 ("**Landlord Contribution**"). Any excess cost shall be borne solely by Tenant and shall be paid to Landlord within 10 business days following Landlord's billing for such excess cost. Tenant understands and agrees that any portion of the Landlord Contribution not utilized by Tenant as part of the single improvement project on or before December 31, 2016 shall inure to the benefit of Landlord and Tenant shall not be entitled to any credit or payment or to apply any such savings toward additional work. Notwithstanding the foregoing, Tenant may utilize a portion of the Landlord Contribution not to exceed $22,354.00 toward the out-of-pocket expenses incurred by Tenant for relocating to the Premises, including furniture moving and data cabling costs ("**Moving Allowance**"). Tenant shall be reimbursed for such expenses by submitting copies of all supporting third-party invoices to Landlord by December 31, 2016. Landlord shall reimburse Tenant in one installment within 30 days following receipt of all such invoices. Tenant understands and agrees that should the cost of the completion of the tenant improvements be less than the maximum amount provided for the Landlord Contribution, then subject to Tenant's foregoing right to apply same to relocation costs in a timely manner as provided above, such savings shall inure to the benefit of Landlord and Tenant shall not be entitled to any credit or payment or to apply the savings toward additional work.

It is understood that the Tenant Improvements may be done during Tenant's occupancy of the Expansion Space. In this regard, Tenant agrees to assume any risk of injury, loss or damage which may result and that no rental abatement shall result while the Tenant Improvements are completed in the Premises.

VI. **Parking.** Notwithstanding any contrary provision in Exhibit C to the Lease, "Parking," effective as of the Expansion Effective Date, Landlord shall lease to Tenant, and Tenant shall lease from Landlord, an additional 45 unreserved parking passes at the rate of $0.00 per pass, per month through the Expiration Date. Thereafter, the parking charge shall be at Landlord's scheduled parking rates from time to time.

VII. **SDN List**. Tenant hereby represents and warrants that neither Tenant nor any officer, director, employee, partner, member or other principal of Tenant (collectively, "**Tenant Parties**") is listed as a Specially Designated National and Blocked Person ("**SDN**") on the list of such persons and entities issued by the U.S. Treasury Office of Foreign Assets Control (OFAC). In the event Tenant or any Tenant Party is or becomes listed as an SDN, Tenant shall be deemed in breach of this Lease and Landlord shall have the right to terminate the Lease immediately upon written notice to Tenant.

VIII. **Fitness Center and Shower Facility**. Subject to the provisions of this Section VIII, so long as Tenant is not in default under the Lease, and provided Tenant's employees execute Landlord's standard waiver of liability form and pay the applicable one time or monthly fee, if any, then Tenant's employees (the "**Fitness Center Users**") shall be entitled to use the fitness center (the "**Fitness Center**") and the shower facility (the "**Shower Facility**") located at the Project. No separate charges shall be assessed to Fitness Center Users for the use of the Fitness Center (with the exception of towel/laundry fees, if any) during the initial Term of the Lease, provided, however, that the costs of operating, maintaining and repairing the Fitness Center shall be included as part of Operating Expenses. The use of the Fitness Center and Shower Facility shall be subject to the reasonable rules and regulations (including rules regarding hours of use) established from time to time by Landlord. Landlord and Tenant acknowledge that the use of the Fitness Center by the Fitness Center Users shall be at their own risk and that the terms and provisions of Section 10.3 of the Lease shall apply to Tenant and the Fitness Center User's use of the Fitness Center. Tenant acknowledges that the provisions of this Section shall not be deemed to be a representation by Landlord that Landlord shall continuously maintain the Fitness Center (or any other fitness facility) and Shower Facility throughout the Term of the Lease, and Landlord shall have the right, at Landlord's sole discretion, to expand, contract, eliminate or otherwise modify the Fitness Center. No expansion, contraction, elimination or modification of the Fitness Center, and no termination of Tenant's or the Fitness Center Users' rights to the Fitness Center shall entitle Tenant to an abatement or reduction in Basic Rent constitute a constructive eviction, or result in an event of default by Landlord under the Lease. Tenant hereby voluntarily releases, discharges, waives and relinquishes any and all actions or causes of action for personal injury or property damage occurring to Tenant or its employees or agents arising as a result of the use of the Fitness Center and Shower Facility, or any activities incidental thereto, wherever or however the same may occur, and further agrees that Tenant will not prosecute any claim for personal injury or property damage against Landlord or any of its officers, agents, servants or employees for any said causes of action, except in cases of Landlord's gross negligence or willful misconduct. It is the intention of Tenant with respect to the Fitness Center and Shower Facility to exempt and relieve Landlord from liability for personal injury or property damage caused by negligence of Tenant.

IX. **Rules and Regulations**. The following shall be added to Exhibit E of the Lease:

"23. Fitness Center Rules. Tenant shall cause its employees (whether members or prospective members of the Fitness Center) to comply with the following Fitness Center rules and regulations (subject to change from time to time as Landlord may reasonably determine):

(a) Membership in the Fitness Center is open to the tenants of Landlord or its affiliates only. No guests will be permitted to use the Fitness Center without the prior written approval of Landlord or Landlord's representative.

(b) Fitness Center users are not allowed to be in the Fitness Center other than the hours designated by Landlord from time to time. Landlord shall have the right to alter the hours of use of the Fitness Center, at Landlord's reasonable discretion.

(c) All Fitness Center users must execute Landlord's Waiver of Liability prior to use of the Fitness Center and agree to all terms and conditions outlined therein.

(d) Individual membership and guest keycards to the Fitness Center shall not be shared and shall only be used by the individual to whom such keycard was issued. Failure to abide by this rule may result in immediate termination of such Fitness Center user's right to use the Fitness Center.

(e) All Fitness Center users and approved guests must have a pre-authorized keycard to enter the Fitness Center. A pre-authorized keycard shall not be issued to a prospective Fitness Center user until receipt by Landlord of Landlord's initial fee, if any, for use of the Fitness Center by such Fitness Center user(s).

(f) Use of the Fitness Center is a privilege and not a right. Failure to follow gym rules or to act inappropriately while using the facilities shall result in termination of Tenant's Fitness Center privileges."

X. **Right to Extend.** Section 1 (Right to Extend) of Exhibit F of the Lease shall apply to the Expansion Space.

XI. **Project Description**. "Project Description: Eastgate Technology Park (as shown on Exhibit Y to this Lease)" set forth in Item 2 of the Basic Lease Provisions shall be deleted in its entirety and "Project Description: Eastgate (as shown on Exhibit Y to this Lease)" shall be substituted in lieu thereof. In addition, Exhibit Y to the Lease shall be deleted and **Exhibit C** to this Amendment shall be substituted in lieu thereof.

XII. **GENERAL.**

A. Effect of Amendments. The Lease shall remain in full force and effect except to the extent that it is modified by this Amendment.

B. Entire Agreement. This Amendment embodies the entire understanding between Landlord and Tenant and can be changed only by a writing signed by Landlord and Tenant. There have been no additional oral or written representations or agreements. Under no circumstances shall Tenant be entitled to any rent abatement, improvement allowance, leasehold improvements, or any similar economic incentives that may have been provided Tenant in connection with entering into the Lease, unless specifically set forth in this Amendment.

C. Counterparts; Digital Signatures. If this Amendment is executed in counterparts, each is hereby declared to be an original; all, however, shall constitute but one and the same amendment. In any action or proceeding, any photographic, photostatic, or other copy of this Amendment may be introduced into evidence without foundation. The parties agree to accept a digital image (including but not limited to an image in the form of a PDF, JPEG, GIF file, or other e-signature) of this Amendment, if applicable, reflecting the execution of one or both of the parties, as a true and correct original.

D. Defined Terms. All words commencing with initial capital letters in this Amendment and defined in the Lease shall have the same meaning in this Amendment as in the Lease, unless they are otherwise defined in this Amendment.

E. Authority. If Tenant is a corporation, limited liability company or partnership, or is comprised of any of them, each individual executing this Amendment for the corporation, limited liability company or partnership represents that he or she is duly authorized to execute and deliver this Amendment on behalf of such entity and that this Amendment is binding upon such entity in accordance with its terms.

F. Certified Access Specialist. As of the date of this Amendment, there has been no inspection of the Building and Project by a Certified Access Specialist as referenced in Section 1938 of the California Civil Code.

G. Attorneys' Fees. The provisions of the Lease respecting payment of attorneys' fees shall also apply to this Amendment.

H. Brokers. Article XVIII of the Lease is amended to provide that the parties recognize the following parties as the brokers who negotiated this Amendment, and agree that Landlord shall be responsible for payment of brokerage commissions to such brokers pursuant to its separate agreements with such brokers: Irvine Realty Company ("**Landlord's Broker**") is the agent of Landlord exclusively and Newmark Grubb Knight Frank ("**Tenant's Broker**") is the agent of Tenant exclusively. By the execution of this Amendment, each of Landlord and Tenant hereby acknowledge and confirm (a) receipt of a copy of a Disclosure Regarding Real Estate Agency Relationship conforming to the requirements of California Civil Code 2079.16, and (b) the agency relationships specified herein, which acknowledgement and confirmation is expressly made for the benefit of Tenant's Broker. By the execution of this Amendment, Landlord and Tenant are executing the confirmation of the agency relationships set forth herein. The warranty and indemnity provisions of Article XVIII of the Lease, as amended hereby, shall be binding and enforceable in connection with the negotiation of this Amendment.

I. Execution of Amendment. Submission of this Amendment by Landlord is not an offer to enter into this Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Amendment until Landlord has executed and delivered the same to Tenant.

J. Nondisclosure of Terms. Tenant acknowledges and agrees that the terms of this Amendment are confidential and constitute proprietary information of Landlord. Disclosure of the terms could adversely affect the ability of Landlord to negotiate other leases and impair Landlord's relationship with other tenants. Accordingly, Tenant agrees that it, and its partners, officers, directors, employees and attorneys, shall not intentionally and voluntarily disclose the terms and conditions of the Lease, as amended, to any other tenant or apparent prospective tenant of the Building or Project, either directly or indirectly, without the prior written consent of Landlord, provided, however, that Tenant may disclose the terms of this Amendment to prospective subtenants or assignees under the Lease, as amended, or pursuant to any legal requirement, including Tenant's obligations under the rules and regulations of the Securities and Exchange Commission.

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Amendment as of the day and year first above written.

LANDLORD: TENANT:

IRVINE EASTGATE OFFICE II LLC
a Delaware limited liability company

By: /s/ Steven M. Case
Steven M. Case
Executive Vice President
Office Properties

By: /s/Michael T. Bennett
Michael T. Bennett
Senior Vice President, Operations
Office Properties

INTERCEPT PHARMACEUTICALS, INC.
a Delaware corporation

By: /s/ Sandip Kapadia

Printed Name: Sandip Kapadia

Title: Chief Financial Officer

By: /s/ Bryan Yoon

Printed Name: Bryan Yoon

Title: Senior Vice President, Legal Affairs

EXHIBIT A

OUTLINE AND LOCATION OF EXPANSION SPACE

4780 Eastgate Mall Road, Suite 250

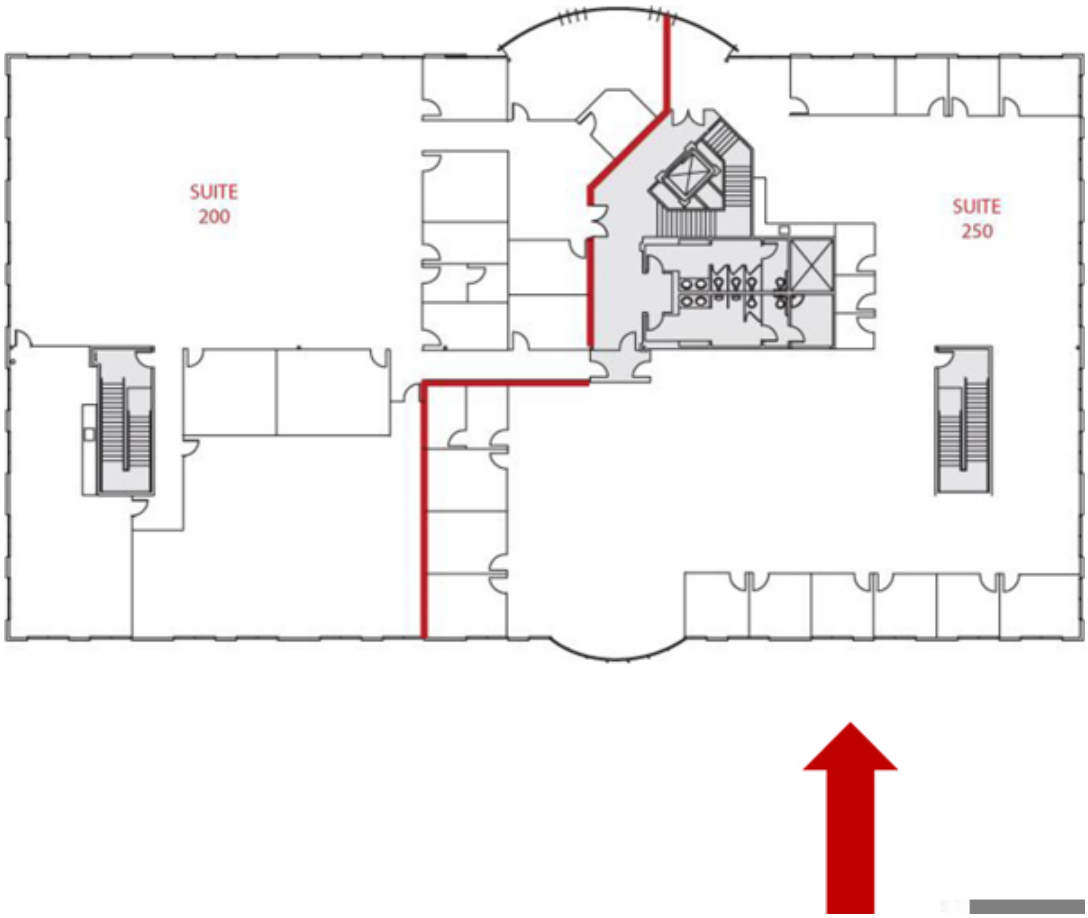

EXHIBIT B

Form Letter of Credit:

……

……

IF THIS LANGUAGE FOR THE STANDBY LETTER OF CREDIT IS TO BE USED THEN THE OBLIGOR/APPLICANT MUST SIGNIFY THEIR APPROVAL BY SIGNING-OFF ON THIS EXHIBIT.

APPROVED AS ISSUED
COMPANY: _____

By: **X** _____ _____
AUTHORIZED SIGNATURE OF OBLIGOR/APPLICANT ***DATE***

……

CITIBANK, N.A. HAS PREPARED THIS DRAFT UPON REQUEST AND BASED ON INFORMATION SUPPLIED TO IT. NO REPRESENTATION OR COMMITMENT IS MADE BY CITIBANK, N.A. REGARDING THE ACCURACY OR SUITABILITY OF THIS DRAFT FOR ITS INTENDED PURPOSE

……

DATE:

ISSUING BANK:
CITIBANK, N.A.
C/O ITS SERVICER, CITICORP NORTH AMERICA, INC.
3800 CITIBANK CENTER, BUILDING B, 3RD FLOOR
TAMPA, FL 33610

BENEFICIARY:
THE IRVINE COMPANY, LLC
550 NEWPORT CENTER DRIVE
NEWPORT BEACH, CA 92660
ATTN: SENIOR VP, PROPERTY OPERATIONS, IRVINE OFF. PROP.

APPLICANT:
INTERCEPT PHARMACEUTICALS, INC.
450 W 15TH ST, SUITE 505
NEW YORK, NY 10011

LETTER OF CREDIT NO.

GENTLEMEN:

BY ORDER OF OUR CLIENT, INTERCEPT PHARMACEUTICALS, INC. (THE "APPLICANT"), WE HEREBY OPEN OUR IRREVOCABLE STANDBY LETTER OF CREDIT NO. _____, IN YOUR FAVOR FOR AN AMOUNT NOT TO EXCEED IN AGGREGATE **USD26,679.00** (TWENTY SIX THOUSAND SIX HUNDRED SEVENTY NINE AND 00/100 U.S. DOLLARS), EFFECTIVE IMMEDIATELY AND EXPIRING AT THE OFFICE OF OUR SERVICER, CITICORP NORTH AMERICA, INC. AT 3800 CITIBANK CENTER, BUILDING B, 3RD FLOOR, TAMPA, FLORIDA 33610 ATTN. STANDBY LETTER OF CREDIT UNIT OR SUCH OTHER OFFICE AS WE MAY ADVISE YOU FROM TIME TO TIME (THE "OFFICE"), **ON APRIL 14, 2015.**

FUNDS HEREUNDER ARE AVAILABLE TO YOU AGAINST PRESENTATION OF YOUR SIGHT DRAFT(S), DRAWN ON US, MENTIONING THEREON OUR LETTER OF CREDIT NUMBER _____, ACCOMPANIED BY YOUR WRITTEN AND DATED STATEMENT, SIGNED BY AN AUTHORIZED OFFICER OF YOUR COMPANY, STATING THE FOLLOWING:

"WE HEREBY CERTIFY THAT THE AMOUNT OF ANY DRAFT(S) DRAWN HEREUNDER REPRESENTS FUNDS DUE AND PAYABLE BECAUSE A DEFAULT HAS OCCURRED UNDER THAT CERTAIN LEASE AGREEMENT BETWEEN INTERCEPT PHARMACEUTICALS, INC. (THE "TENANT"), AND THE IRVINE COMPANY, LLC (THE "LANDLORD"), DATED _____; WRITTEN NOTICE OF SUCH DEFAULT WAS DULY GIVEN TO THE TENANT AND ALL APPLICABLE GRACE PERIODS EXPIRED UNDER SAID LEASE."

IT IS A CONDITION OF THIS LETTER OF CREDIT THAT IT SHALL BE DEEMED AUTOMATICALLY EXTENDED, WITHOUT AMENDMENT, FOR ADDITIONAL PERIOD(S) OF ONE YEAR FROM THE EXPIRY DATE HEREOF, OR ANY FUTURE EXPIRATION DATE, BUT NOT BEYOND **NOVEMBER 01, 2019**, UNLESS AT LEAST **SIXTY (60) DAYS** PRIOR TO ANY EXPIRATION DATE WE NOTIFY YOU BY REGISTERED MAIL OR BY ANY OTHER RECEIPTED MEANS THAT WE ELECT NOT TO CONSIDER THIS LETTER OF CREDIT RENEWED FOR ANY SUCH ADDITIONAL PERIOD, WHEREUPON YOU MAY DRAW FOR THE AVAILABLE AMOUNT UNDER THIS LETTER OF CREDIT BY MEANS OF YOUR SIGHT DRAFT(S), DRAWN ON US, MENTIONING OUR LETTER OF CREDIT NUMBER.

IT IS A CONDITION OF THIS LETTER OF CREDIT THAT IT IS TRANSFERABLE AND MAY BE TRANSFERRED IN ITS ENTIRETY, BUT NOT IN PART, AND MAY BE SUCCESSIVELY TRANSFERRED BY YOU OR ANY TRANSFEREE HEREUNDER TO A SUCCESSOR TRANSFEREE(S). TRANSFER UNDER THIS LETTER OF CREDIT TO SUCH TRANSFEREE SHALL BE EFFECTED UPON PRESENTATION TO US OF THE ORIGINAL OF THIS LETTER OF CREDIT AND ANY AMENDMENTS HERETO ACCOMPANIED BY A REQUEST DESIGNATING THE TRANSFEREE IN THE FORM OF EXHIBIT "A" ATTACHED HERETO APPROPRIATELY COMPLETED, ALONG WITH PAYMENT OF 1/4 OF ONE PERCENT (MINIMUM $250) AS A TRANSFER FEE.

WE HEREBY AGREE TO HONOR EACH DRAFT DRAWN UNDER AND IN COMPLIANCE WITH THE TERMS AND CONDITIONS OF THIS LETTER OF CREDIT IF PRESENTED, AS SPECIFIED, AT OUR OFFICE ON OR BEFORE EXPIRATION DATE.

IN ADDITION, PRESENTATION OF SUCH DRAFT AND CERTIFICATE MAY ALSO BE MADE BY FAX TRANSMISSION TO FAX NO. OR SUCH OTHER FAX NUMBER IDENTIFIED BY CITIBANK, N.A. IN A WRITTEN NOTICE TO YOU. TO THE EXTENT A PRESENTATION IS MADE BY FAX TRANSMISSION, YOU MUST (I) PROVIDE TELEPHONE NOTIFICATION THEREOF TO CITIBANK, N.A. (PHONE NO.) PRIOR TO OR SIMULTANEOUSLY WITH THE SENDING OF SUCH FAX TRANSMISSION AND (II) SEND THE ORIGINAL OF SUCH DRAFT AND CERTIFICATE TO CITIBANK, N.A. BY OVERNIGHT COURIER, AT THE ADDRESS PROVIDED ABOVE FOR PRESENTATION OF DOCUMENTS , PROVIDED HOWEVER, THAT CITIBANK, N.A.'S RECEIPT OF SUCH TELEPHONE NOTICE OR ORIGINAL DOCUMENTS SHALL NOT BE A CONDITION TO PAYMENT HEREUNDER.

SHOULD YOU HAVE OCCASION TO COMMUNICATE WITH US REGARDING THIS LETTER OF CREDIT, PLEASE DIRECT YOUR CORRESPONDENCE TO OUR OFFICE, MAKING SPECIFIC MENTION OF THE LETTER OF CREDIT NUMBER INDICATED ABOVE. FOR INQUIRIES YOU MAY CONTACT US AT OR VIA SWIFT.

ALL PARTIES TO THIS LETTER OF CREDIT ARE ADVISED THAT THE U.S. GOVERNMENT HAS IN PLACE CERTAIN SANCTIONS AGAINST CERTAIN COUNTRIES, INDIVIDUALS, ENTITIES, AND VESSELS. CITIGROUP ENTITIES, INCLUDING BRANCHES AND, IN CERTAIN CIRCUMSTANCES, SUBSIDIARIES, ARE/WILL BE PROHIBITED FROM ENGAGING IN TRANSACTIONS OR OTHER ACTIVITIES WITHIN THE SCOPE OF APPLICABLE SANCTIONS

EXCEPT AS FAR AS OTHERWISE EXPRESSLY STATED HEREIN, THIS STANDBY LETTER OF CREDIT IS SUBJECT TO THE INTERNATIONAL STANDBY PRACTICES (“ISP98”), INTERNATIONAL CHAMBER OF COMMERCE, PUBLICATION NO. 590, AND AS TO MATTERS NOT GOVERNED BY THE ISP98, SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK AND APPLICABLE U.S. FEDERAL LAW.

Exhibit A
Request for Full Transfer
Relinquishing all Rights as Beneficiary

(This form is to be used when the Letter of Credit is to be Transferred in its entirety and, no substitution of invoices is involved and, no rights are to be retained by the undersigned Beneficiary.)

Citicorp North America Inc., **Date:**
As Servicer for Citibank, N.A.
3800 Citibank Center, Bldg. B, 3rd Fl.
Tampa, FL 33610

Re: L/C No. _____

Issued by: CITIBANK, N.A.

Citibank, N.A. **Ref: _____**

Gentlemen:

Receipt is acknowledged of the original instrument which you forwarded to us relative to the issuance of a Letter of Credit (herein called the "Credit") bearing your reference number as above in favor of ourselves and/or Transferees and we hereby request you to transfer the said Letter of Credit, in its entirety, to:

_____

whose address is _____

_____

(Optional) Please advise Beneficiary through the below indicated Advising Bank:

_____

_____

We are returning the original instrument to you herewith in order that you may deliver it to the Transferees together with your customary letter of transfer.

It is understood that any amendments to the Letter of Credit which you may receive are to be advised by you directly to the Transferees and that the drafts and documents of the Transferees, if issued in accordance with the conditions of the Letter of Credit, are to be forwarded by you directly to the party for whose account the credit was opened (or any intermediary) without our intervention.

(continued on page 2)

Citibank, N.A. **reference _____**

We understand that the Transfer charge is 1/4 of 1% on the amount being transferred (minimum $250.00) and in addition thereto we agree to pay to you on demand any expenses that may be incurred by you in connection with this transfer.

___ We enclose our check for $ _____ to cover your charges.
(Note: Payment of charges must be in the form of a certified check if not drawn on *Citibank, N.A.*)

___ We authorize you to charge our *Citibank N.A.* account No. _____

SIGNATURE GUARANTEED

The First Beneficiary's signature(s) with title(s) conforms with that on file with us and such is/are authorized for the execution of this instrument.

Sincerely yours,

(Name of Bank)	**(Name of First Beneficiary)**
(Bank Address)	**(Telephone Number)**
(City, State, Zip Code)	**(Authorized Name and Title)**
(Telephone Number)	**(Authorized Signature)**
(Authorized Name and Title)	**(Authorized Name and Title)** **(If applicable)**
(Authorized Signature)	**(Authorized Signature)** **(If applicable)**

Eastgate Technology Park
Site Plan

Exhibit 10.8

Execution Version

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

MANUFACTURING AND SUPPLY AGREEMENT

between

INTERCEPT PHARMA EUROPE LTD.

and

PHARMAZELL GMBH

This **MANUFACTURING AND SUPPLY AGREEMENT** (this "Agreement"), dated the last date of signature (the "**Effective Date**"), is made by and between **Intercept Pharma Europe Ltd**., having a location at 2 Pancras Square, Floor 1, London, United Kingdom N1C 4AG ("**Intercept**"), and, solely for purposes of Section 10.19, Intercept Pharmaceuticals, Inc. ("**Intercept Parent**"), and PharmaZell GmbH, a corporation organized under the laws of Germany ("**PharmaZell**"). Intercept and PharmaZell are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, pursuant to a certain Development Agreement by and between the Parties dated August 18, 2010, the Parties collaborated to develop a synthesis pathway for the manufacture, production, and validation of an active pharmaceutical ingredient for Intercept referred to as [**]; and

WHEREAS, Intercept and PharmaZell now wish to enter into this Agreement to arrange for the manufacture and supply by PharmaZell to Intercept of the API (as defined below), on the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises, the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

As used herein, the following terms shall have the following meanings:

1.1 "**Adjustment Date**" has the meaning set forth in Section 4.4(a).

1.2 "**Adverse Event**" means (a) any finding from tests in laboratory animals or in vitro that suggests a significant risk for human subjects including reports of mutagenicity, teratogenicity or carcinogenicity, (b) any undesirable, untoward or noxious event or experience associated with the clinical, commercial or other use, or occurring following application of a Product to humans, whether expected and whether considered related to or caused by such Product, including such an event or experience as occurs in the course of the use of such Product in professional practice, in a clinical trial, whether accidental or intentional, from abuse, from withdrawal or from a failure of expected therapeutic action of such Product, and (c) those events or experiences that are required to be reported to the Regulatory Authorities under corresponding Applicable Law.

1.3 "**Affiliate**" of a Person means any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, such first Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with", means to possess the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract or otherwise.

1.4 "**Agreement**" has the meaning set forth in the preamble hereto, including all Work Orders provided by Intercept.

1.5 "**API**" means the active pharmaceutical ingredient [**].

1.6 "**API Precursor**" means any intermediary, ingredient, composition or element [**] that arises or is created or produced following production of the Intermediary during the Manufacture of the API.

1.7 "**API Specifications**" means the specifications for the API to be Manufactured by PharmaZell and supplied to Intercept hereunder as such specifications are set forth in the Quality Agreement, as the same may be amended from time to time.

1.8 "**Applicable Law**" means all laws, statutes, rules, codes, regulations, requirements, orders, judgments and ordinances of any Regulatory Authority, including the FFDCA.

1.9 "**Business Day**" means a day other than a Saturday or a Sunday on which banks in New York, New York and Munich, Germany are open for the conduct of regular banking business.

1.10 "**Calendar Quarter**" means each period of three (3) consecutive calendar months commencing on 1 January, 1 April, 1 July, and 1 October, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on September 30, 2016, and the last Calendar Quarter of the Term shall commence on the first day of the calendar quarter in which the Term ends and end on the last day of the Term.

1.11 "**Calendar Year**" means each successive period of twelve (12) consecutive calendar months commencing on 1 January and ending on 31 December, except that the first Calendar Year of the Term shall commence on the Effective Date and end on 31 December 2016, and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.12 "**Certificate of Analysis**" or "**COA**" has the meaning set forth in the Quality Agreement.

1.13 "**Certificate of Compliance**" or "**COC**" has the meaning set forth in the Quality Agreement.

1.14 "**CMC Data**" means the chemistry, manufacturing and controls data required by Applicable Law to be included in a New Drug Application (as defined in the FFDCA and the regulations promulgated thereunder) for a Product or in any other Regulatory Approval outside the United States.

1.15 "**Confidential Information**" means any and all information or material that, at any time before or after the Effective Date, has been or is provided or communicated to the Receiving Party by or on behalf of the Disclosing Party (including by a third party) pursuant to this Agreement or in connection with the transactions contemplated hereby or any discussions or negotiations with respect thereto; any data, ideas, concepts or techniques contained therein; and any modifications thereof or derivations therefrom. Confidential Information may be disclosed either orally, visually, electronically, in writing, by delivery of Materials containing Confidential Information or in any other form now known or hereafter invented.

1.16 "**Control**" means, with respect to any item of information, Invention, Regulatory Documentation, patent, trademark or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of any license and other grants hereunder), to assign or grant a license, sublicense or other right to or under, or perform other acts in respect of, such information, Invention, Regulatory Documentation, patent, trademark or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any third party.

1.17 "**Deficiency**" has the meaning set forth in Section 2.3(c).

1.18 "**Delivery Date**" means the date the API leaves the Facility for shipment to Intercept.

1.19 "**Disclosing Party**" means the Party disclosing Confidential Information.

1.20 "**Disqualification**" has the meaning set forth in Section 6.2(c).

1.21 "**Effective Date**" has the meaning set forth in the preamble hereto.

1.22 "**Employee Inventions**" has the meaning set forth in Section 5.1(g).

1.23 "**Existing Work Orders**" has the meaning set forth in Section 2.2(a).

1.24 "**Exploit**" means to make, have made, import, use, sell, offer for sale or otherwise dispose of a compound, product or process, including all discovery, research, development, commercialization, registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, exportation, transportation, distribution, promotion and marketing of such compound, product or process.

1.25 "**Facility**" means a Manufacturing facility of PharmaZell located at (i) [**], (ii) [**], and/or (iii) such other facility as the Parties may agree to in writing from time to time.

1.26 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.27 "**FFDCA**" means the U.S. Federal Food, Drug, and Cosmetic act codified at 21 U.S.C. § 301 et seq., as may be amended from time to time.

1.28 "**Gesetz über Arbeitnehmererfindungen**" has the meaning set forth in Section 5.1(g).

1.29 "**GMI**" means the German Producer Price Index ("Index der Erzeugerpreise gewerblicher Produkte") for pharmaceutical preparations, as compiled and published by the Bureau of Labor Statistics of the United States Department of Labor and using the latest version of data published as of the date of adjustment.

1.30 "**GMP**" or "**cGMP**" means all applicable standards relating to manufacture of pharmaceutical products, including, as applicable current Good Manufacturing Practices as they apply to the manufacture of Supplied Material, and including (i) standards promulgated by any Regulatory Authority having jurisdiction over the Manufacture of the Supplied Material, in the form of Applicable Laws, including the U.S. current Good Manufacturing Practices regulations promulgated by the FDA, as described in 21 U.S.C. 351, 21 C.F.R. Parts 210 and 211, as amended, and any successor provision thereto and ICH Q7 – Good Manufacturing Practice for Active Pharmaceutical Ingredients; (ii) standards promulgated by any Regulatory Authority having jurisdiction over the Manufacture of the Supplied Material, in the form of draft or final guidance documents (including advisory opinions, compliance policy guides and guidelines); and (iii) such other industry standards as may be agreed upon by the Parties in the Specifications (as defined and set forth in the Quality Agreement).

1.31 "**ICC Rules**" has the meaning set forth in Section 10.8(a).

1.32 "**Indemnification Claim Notice**" has the meaning set forth in Section 9.3(a).

1.33 "**Indemnified Party**" has the meaning set forth in Section 9.3(a).

1.34 "**Indemnifying Party**" has the meaning set forth in Section 9.3(a).

1.35 "**Initial Term**" has the meaning set forth in Section 8.1.

1.36 "**Intercept**" has the meaning set forth in the preamble hereto.

1.37 "**Intercept Indemnified Parties**" has the meaning set forth in Section 9.1.

1.38 "**Intercept Information**" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, technical assistance, designs, assembly procedures, specifications, assays, test methods, analytical methods, and other material or information owned or Controlled by Intercept or its Affiliates (including information received from a third party) as of the Effective Date or at any time during the Term.

1.39 "**Intercept Intellectual Property**" has the meaning set forth in Section 5.1(a).

1.40 "**Intercept Materials**" means those Materials identified on Schedule 1.40 to be supplied by Intercept to PharmaZell for Manufacture of the API.

1.41 "**Intermediary**" means [**].

1.42 "**Invention**" means any discovery, improvement, process, formula, data, information, invention, know-how, trade secret, procedure, device, or other intellectual property, whether or not protectable under patent, trademark, copyright or similar laws, including any enhancement in the manufacture, formulation, ingredients, preparation, presentation, means of delivery, dosage or packaging of a compound or product or any discovery or development of a new indication for a compound or product.

1.43 "**Joint Invention Patents**" has the meaning set forth in Section 5.2(c)(i).

1.44 "**Joint Inventions**" mean any and all Inventions that are or have been created, conceived, discovered, developed or otherwise made jointly by or on behalf of the Parties, but excluding Specified Inventions.

1.45 "**Latent Defect**" means any deficiency (including any Supplied Material that fails to meet the Supplied Material Warranty or other quality requirements set forth in the Quality Agreement) that is not readily determinable upon a reasonable inspection of the Supplied Material (based on physical inspection, identity test and review of the certificate of analysis).

1.46 "**Losses**" has the meaning set forth in Section 9.1.

1.47 "**Manufacture**" and "**Manufacturing**" means all steps, processes, activities and operations from purchase of Materials, through production, quality control, release and storage, to distribution of API, and the related controls.

1.48 "**Material(s)**" means all ingredients, raw materials, packaging and labeling components, and all other supplies of any kind, required or used in connection with the Manufacturing of Supplied Material.

1.49 "**Minimum Annual Requirement**" has the meaning set forth in Section 2.2(b).

1.50 "**Minimum Percentage Requirement**" has the meaning set forth in Section 2.2(b).

1.51 "**Other PharmaZell Invention Patents**" has the meaning set forth in Section 5.2(b)(i).

1.52 "**Other PharmaZell Inventions**" means [**].

1.53 "**Party**" and "**Parties**" has the meaning set forth in the preamble hereto.

1.54 "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.55 "**PharmaZell**" has the meaning set forth in the preamble hereto.

1.56 "**PharmaZell Indemnified Parties**" has the meaning set forth in Section 9.2.

1.57 "**Policies**" has the meaning set forth in Section 9.4(a).

1.58 "**Products**" means the finished product containing the API.

1.59 "**Purchase Price**" has the meaning set forth in Section 4.1(a).

1.60 "**Quality Agreement**" means the quality assurance agreement dated August 20, 2014 entered into by the Parties.

1.61 "**Quality Standards**" means the obligations set forth in the Quality Agreement as well as compliance with applicable environmental/health/safety requirements and cGMP requirements.

1.62 "**Receiving Party**" means the Party receiving Confidential Information.

1.63 "**Recipients**" has the meaning set forth in Section 7.1.

1.64 "**[**]**" means [**].

1.65 "**Regulatory Approval**" means, with respect to any particular country or other jurisdiction, as applicable any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary for the Exploitation of a Product in such country or jurisdiction, including, where applicable, (a) approval of a Product in such country or jurisdiction, including any marketing authorization and supplements and amendments thereto, including an approved New Drug Application as defined in the FFDCA or any corresponding foreign application, registration or certification necessary or reasonably useful to market any Product in a country or regulatory jurisdiction; (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labeling approval; and (d) technical, medical and scientific licenses.

1.66 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of Supplied Material or a product in any country or other jurisdiction, including those responsible for granting approvals for the performance of services by PharmaZell to Intercept or for issuing regulations pertaining to the manufacture or use of the Supplied Material or Product in the intended country of use, including the FDA.

1.67 "**Regulatory Documentation**" means as applicable (a) submissions to any Regulatory Authority, including investigational new drug applications, New Drug Applications (as defined in the FFDCA and the regulations promulgated thereunder), correspondence with regulatory agencies (registrations and licenses, regulatory drug lists, advertising and promotion documents), periodic safety update reports, adverse event files, complaint files and manufacturing records and, if applicable, any updates or supplements to any of the foregoing and (b) any minutes or contact logs with respect to any telephone conferences or in-person meetings conducted with any Regulatory Authority relating to the subject matter described in clause (a) of this sentence.

1.68 "**Release Testing**" means all testing of the quality attributes of the Supplied Material in accordance with the Specifications and the Quality Agreement.

1.69 "**Renewal Period**" has the meaning set forth in Section 8.1.

1.70 "**Required Manufacturing Changes**" has the meaning set forth in Section 3.6(b).

1.71 "**Representative**" has the meaning set forth in Section 6.2(a).

1.72 "**Services**" means the Manufacturing, supply and other services performed under this Agreement.

1.73 "**Specifications**" means the API Specifications.

1.74 "**Specified Invention Patents**" has the meaning set forth in Section 5.2(a)(i).

1.75 "**Specified Inventions**" means [**].

1.76 "**Supplied Material**" means the API.

1.77 "**Supplied Material Warranty**" has the meaning set forth in Section 6.2(b).

1.78 "**Term**" has the meaning set forth in Section 8.1.

1.79 "**Testing Laboratory**" means an independent third party laboratory engaged by the Parties to test conformance of the Supplied Material to the Specifications in accordance with the terms set forth in the Quality Agreement.

1.80 "**Third Party Claim**" has the meaning set forth in Section 9.1.

1.81 "**Total Commercial Volume Requirements**" means, for purposes of calculating Intercept's total commercial volume requirements for Supplied Material for a given Calendar Year, the total amount of Supplied Material [**].

1.82 "**United States**" means the United States of America, its territories and possessions, including the District of Columbia and Puerto Rico.

1.83 "**Work Order**" means a written work order that sets forth, with respect to the period covered thereby, (a) the quantities of each Supplied Material to be processed and delivered by PharmaZell to Intercept or its designee, (b) the required Delivery Dates therefor, and (c) the required delivery locations therefor, in the form attached hereto as Schedule 1.83.

ARTICLE 2
MANUFACTURING AND SUPPLY

2.1 Supply Obligations.

(a) Generally. Subject to the terms and conditions hereof, PharmaZell shall Manufacture and supply to Intercept such quantities of Supplied Material as Intercept may from time to time during the Term order. Such Manufacture and supply shall be in accordance with Applicable Laws, the Specifications, the Regulatory Documentation, Regulatory Approvals and the terms of this Agreement and the Quality Agreement.

(b) Exclusivity of PharmaZell. To the maximum extent permitted by Applicable Law, without the written consent of Intercept, PharmaZell shall not, and PharmaZell shall cause its Affiliates not to, distribute, market, promote, offer for sale, sell, supply or Manufacture API or any API Precursor, directly or indirectly, whether alone or in combination with other molecules or compounds, whether as a raw material or as a finished product, and whether at wholesale or retail, to any Person other than Intercept, its Affiliates or designees.

(c) Purchase Obligations of Intercept. Subject to the Minimum Percentage Requirement and the Minimum Annual Requirement set forth in Section 2.2(b), this Agreement shall not limit Intercept's right to obtain Supplied Material from any third party. PharmaZell acknowledges that Intercept has the right to enter into arrangements with one or more third parties to act as additional sources of Supplied Material.

(d) Subcontractors. PharmaZell may not subcontract with any third party to perform any of its obligations hereunder without the prior written consent of Intercept; provided that with respect to the existing subcontractors and activity set forth on Schedule 2.1(d), Intercept hereby agrees that such subcontractors are hereby permitted subcontractors with respect to the activity identified for such subcontractor. PharmaZell shall be solely responsible for the performance of any permitted subcontractor, and for costs, expenses, damages, or losses of any nature arising out of such performance as if such performance had been provided by PharmaZell itself under this Agreement. PharmaZell shall cause any such permitted subcontractor to be bound by, and to comply with, all confidentiality, quality assurance, regulatory and other obligations and requirements of PharmaZell set forth in this Agreement. PharmaZell and its subcontractors may use Intercept Intellectual Property only for the performance of the Services as specified in this Agreement.

2.2 Work Orders.

(a) Existing Work Orders. The Parties acknowledge and agree that Intercept and PharmaZell have, prior to the date hereof, agreed to certain Work Orders with respect to Supplied Materials, including penalties therein for PharmaZell's failure to deliver Supplied Material in accordance with the terms of such Work Orders. The existing Work Orders are attached hereto as Schedule 2.2(a) (the "**Existing Work Orders**"). The Parties acknowledge and agree that PharmaZell shall continue to Manufacture the quantities of Supplied Materials set forth in the Existing Work Orders in accordance with the timelines set forth in the Existing Work Orders; provided, however, the Parties acknowledge and agree that the Supplied Materials Manufactured and supplied under the Existing Work Orders shall be governed by the terms and conditions of this Agreement, and this Agreement supersedes and replaces any term or condition contained in such Existing Work Orders and any term or condition associated with such Existing Work Orders other than the delivery obligations, the price, the shared risk provisions and associated penalties of PharmaZell, which shall continue to apply as specified in the Existing Work Orders.

(b) New Work Orders; Minimum Percentage Requirement. Intercept shall place Work Orders at least [**] months in advance of the requested Delivery Date but no more than [**] months in advance of the requested Delivery Date. With respect to each Work Order, Intercept shall be obligated to purchase, and PharmaZell shall be obligated to deliver, by the required Delivery Date set forth therein such quantities of the Supplied Material as are set forth therein. Intercept agrees to order from PharmaZell at least [**] of Intercept's Total Commercial Volume Requirements for delivery in each of [**] ("**Minimum Percentage Requirement**"); provided that, [**] notwithstanding Intercept's actual Total Commercial Volume Requirements in Calendar Years 2017 and 2018, at a minimum, Intercept shall order at least [**] of Supplied Material to be delivered in each of Calendar Year 2017 and Calendar Year 2018 ("**Minimum Annual Requirement**"). Notwithstanding the foregoing, (i) to the extent that Intercept has ordered a quantity of Supplied Material from PharmaZell but PharmaZell fails for any reason to deliver such quantity within [**] days of the Delivery Date or such Supplied Material is rejected by Intercept pursuant to Section 2.3(c), all such ordered Supplied Material shall be considered Supplied Material that was "ordered and delivered" under the terms of this Section 2.2(b) in calculating the Minimum Percentage Requirement and Minimum Annual Requirement, and (ii) if Intercept's Total Commercial Volume Requirements in a given year are in excess of PharmaZell's capacity to Manufacture such quantity of Supplied Material, then for purposes of calculating Intercept's total volume, the percentage shall be based upon PharmaZell's maximum capacity. In addition, if Intercept has ordered a quantity of Supplied Material from PharmaZell but PharmaZell fails to deliver such quantity as a result of PharmaZell's inability to satisfy the Quality Standards (and PharmaZell is unable to remedy such inability to satisfy the Quality Standards within [**] days) or the Supplied Material is rejected by Intercept pursuant to Section 2.3(c) as a result of PharmaZell's failure to satisfy the Quality Standards, then (i) Intercept's obligation to achieve the Minimum Percentage Requirement and Minimum Annual Requirement shall be suspended until such time as PharmaZell is able to remedy such Quality Standard issue and (ii) Intercept's Minimum Percentage Requirement and Minimum Annual Requirement for such Calendar Year shall be proportionately reduced by the length of the suspension; provided that if PharmaZell is able to remedy the issue with the Quality Standards and deliver Supply Material to Intercept and Intercept accepts the full amount of the delivery despite the proportional reduction, then Intercept's Minimum Annual Requirement and Minimum Percentage Requirement for the subsequent Calendar Year shall be reduced by such proportionate amount. To the extent PharmaZell is responsible for manufacturing the Intermediary and to the extent Intercept is responsible for supplying the [**] to PharmaZell for the manufacture of the Intermediary, Intercept shall ensure timely delivery of the [**] to PharmaZell. In addition, in the event that [**], then Intercept shall have no Minimum Annual Requirement commencing on the date of any such event and for the duration of the Agreement. The Parties agree that the first new work order under the Agreement shall be as specified in Schedule 2.2(b) attached hereto.

(c) Work Order Terms. In the event that the terms of any Work Order are not consistent with or are in addition to the terms of this Agreement, the terms of this Agreement shall prevail. The Parties agree that each Work Order shall be for a minimum of [**] and that Intercept shall attempt to order a batch size of [**]. The Parties further agree that if the Manufacturing is to be done at [**], the size of the batch in a Work Order [**] but otherwise is subject to the terms of this Agreement.

2.3 Delivery Terms; Inspection.

(a) Delivery. PharmaZell shall deliver the quantities of API set forth in each Work Order by the required Delivery Date(s) set forth in such Work Order and in accordance with the reasonable written instructions as such instructions are agreed by the Parties. PharmaZell shall deliver API, DAP (Incoterms 2010), with the delivery address specified by Intercept. Risk of loss and title shall pass to Intercept upon delivery of API as specified in the preceding sentence. In the event Intercept wishes to have an expedited delivery, PharmaZell reserves the right to charge Intercept for the additional costs involved therefor.

(b) Accompanying Documentation. Each delivery of API shall be accompanied by (i) a Certificate of Analysis, (ii) a Certificate of Compliance, (iii) such other documents as may be required pursuant to the Quality Agreement, and (iv) documentation necessary for the sale or export of the API, as applicable.

(c) Inspection. Within [**] days of receipt of a given shipment of Supplied Material, Intercept (or its agent) shall verify on the basis of a visual inspection the quantity of Supplied Material delivered. In addition, Intercept (or its agent) shall inspect at Intercept's discretion (based minimally on physical inspection, identity test and review of the Certificate of Analysis and Certificate of Conformance provided by PharmaZell) the Supplied Material following Delivery for variances and defects; and if Intercept claims that a shipment of Supplied Material did not, at the time of receipt by Intercept, meet the Supplied Material Warranty or the quality requirements set forth in the Quality Agreement (a "**Deficiency**"), Intercept shall notify PharmaZell based on the foregoing inspection within [**] days after receipt of such Supplied Material at Intercept's (or its designee's) site, which notice shall provide the quantities affected, the basis for the claim and other information reasonably necessary for PharmaZell to assess the claim. Notwithstanding the foregoing, if Intercept claims that the Deficiency is a Latent Defect, Intercept shall have the obligation to provide such notification to PharmaZell in writing within [**] days after Intercept's discovery of such Latent Defect (or within [**] days after Intercept is notified in writing by a third party of such Latent Defect, if later). If Intercept and PharmaZell are unable to agree as to whether such Supplied Material contains a Deficiency, the Parties shall cooperate to have the Supplied Materials in dispute analyzed by the Testing Laboratory. The results of the Testing Laboratory shall be final and binding on the Parties on the issue of whether such Supplied Material contains a Deficiency. If the Supplied Materials are determined to not contain a Deficiency, then Intercept shall bear the cost of the Testing Laboratory and pay the Purchase Price with respect to the Supplied Materials in accordance with this Agreement. If the Supplied Materials are determined to contain a Deficiency, then PharmaZell shall bear the cost of the Testing Laboratory, and PharmaZell shall (i) at Intercept's election, either replace the rejected Supplied Materials at no cost to Intercept, or refund to Intercept the Purchase Price paid for such Supplied Materials, and the cost of all Intercept Materials used for such Supplied Materials plus any applicable delivery charge and (ii) reimburse to Intercept all costs associated with any manufacturing and distribution of Products incorporating such Supplied Material, including formulation, packaging, storage and distribution expenses (and including materials used in connection therewith).

2.4 Materials. PharmaZell shall be responsible for auditing and qualifying its supplier(s) of Materials and obtaining supplies of Materials in accordance with the Specifications, Applicable Laws, Regulatory Documentation, Regulatory Approvals and the Quality Agreement. Quality and Regulatory and all GMP related issues shall be defined in the Quality Agreement. At all times during the Term, PharmaZell shall (at its own cost and expense) maintain sufficient amounts of available inventory of Materials (other than Intercept Materials) consistent with industry standards and shelf life requirements of such Materials as may be necessary for PharmaZell to Manufacture Supplied Materials.

2.5 Costs and Expenses. Except as otherwise explicitly set forth herein, PharmaZell shall be solely responsible for all costs and expenses incurred in connection with the Manufacture of Supplied Materials hereunder, including costs and expenses of personnel, quality control testing, Manufacturing facilities and equipment, and Materials. In addition, at PharmZell's cost and expense, PharmaZell shall be entitled to maintain an inventory of safety stock of Supplied Material and any of its intermediates.

2.6 Supply Shortage; Inability to Supply.

(a) In the event that PharmaZell is unable or anticipates it will be unable to supply, in whole or in part, the quantity of Supplied Material as set forth in any Work Order, PharmaZell shall notify Intercept of such inability upon discovery of the same by PharmaZell, including the underlying reasons for such inability, proposed remedial measures and the date such inability is expected to end. In the event that PharmaZell is unable to Manufacture Supplied Material as a result of a shortage of Materials (other than to the extent such shortage is the result of Intercept's failure to provide [**]), then PharmaZell hereby agrees and acknowledges that [**].

(b) In the event that Intercept is unable to provide [**] to PharmaZell within the project timelines agreed to by the Parties, the Parties shall discuss in good faith allowing PharmaZell to manufacture [**] itself and for Intercept to purchase such [**] from PharmaZell.

(c) Nothing contained in this Section 2.6 shall limit any legal, equitable or other rights or remedies that may be available to Intercept on account of any failure of PharmaZell to Manufacture and supply Supplied Materials hereunder.

2.7 Intercept Materials.

(a) PharmaZell shall maintain, handle and store the Intercept Materials in accordance with the cGMP, Applicable Laws and all written instructions as agreed by the Parties. The Intercept Materials shall be stored in a secured area and clearly marked and identified as property of Intercept clearly separated from other products or materials by palette or location. PharmaZell shall be responsible to communicate any necessary information regarding such Intercept Materials (including material safety data sheets and other information provided to PharmaZell relating to the handling and safety of the Intercept Materials) to its employees, agents and representatives engaged in performing the Manufacturing services. PharmaZell shall ensure that Intercept Materials are free and clear of any liens or encumbrances. PharmaZell shall notify Intercept if at any time it believes Intercept Materials have been damaged, lost or stolen.

(b) PharmaZell shall notify Intercept when the inventories of Intercept Materials become insufficient to Manufacture the API, as required under this Agreement. In addition, at the end of each calendar month, PharmaZell shall provide to Intercept a stock reconciliation report of the Intercept Materials, which report shall include: (a) the opening stock of Intercept Materials at the beginning of the month, (b) the receipt of any additional Intercept Materials, (c) the usage of Intercept Materials during the month (including yield loss), and (d) the stock balance of Intercept Materials.

(c) PharmaZell shall use the Intercept Materials solely and exclusively to Manufacture the Supplied Materials under this Agreement and for no other purpose. PharmaZell shall withdraw Intercept Materials from storage on [**].

(d) PharmaZell shall at all times take such measures as are required to protect the Intercept Materials from risk of loss or damage at all stages of the Manufacturing process that are consistent with those measures that PharmaZell utilizes for its own materials but in no event less than are reasonable and customary in the industry. PharmaZell accepts all risk of loss and full responsibility for the condition of Intercept Materials which may be damaged, lost or stolen by PharmaZell or its personnel. PharmaZell shall at all times take such measures as are required to protect the Intercept Materials from risk of loss or damage. Intercept will be responsible for all transportation costs for such Intercept Materials. Notwithstanding the foregoing, PharmaZell shall be financially responsible for any loss of such Intercept Materials to the extent such loss results from (a) breach of this Agreement by PharmaZell, (b) negligence or willful misconduct of PharmaZell, its Affiliates and any permitted subcontractors, in which case PharmaZell shall reimburse Intercept for costs of such Intercept Materials, plus any shipping costs and out-of-pockets costs incurred by or on behalf of Intercept with respect to such Intercept Materials.

(e) PharmaZell shall use its best efforts to obtain standard yields. The standard yields are set forth in Schedule 2.7(e). The allowable annual yield variation from the standard yield for the Intercept Materials shall not be more than [**]. For illustration purposes only, an example yield loss calculation is set forth on Schedule 2.7(e). Concurrently with each invoice of Supplied Materials, PharmaZell shall provide Intercept with a written accounting of the disposition of each yield variation of Intercept Materials. In the event that the yield variation exceeds the agreed upon allowable yield variation or any losses of Intercept Materials are due to the negligence or willful misconduct of PharmaZell, Intercept shall, at the option of Intercept, either receive a reimbursement from PharmaZell or reduce Intercept's payment for the relevant invoice for such Supplied Material in an amount equal to [**]. The Parties shall in good faith reevaluate the standard yield and the annual yield variation at the beginning of each Calendar Year to account for increased efficiencies in the Manufacture of Supplied Material or decreases caused by Required Manufacturing Changes or other agreed changes to the process.

(f) In the event that PharmaZell obtains excess yields of the Intercept Materials, PharmaZell will invoice the excess quantities to Intercept (such excess quantity not to exceed more than [**] of the amount in Intercept's Work Order), and Intercept will accept such delivery and invoice.

(g) To the extent Intercept supplies [**] as part of the Intercept Materials, all such [**] provided by Intercept shall be [**].

ARTICLE 3
QUALITY; COMPLIANCE; REGULATORY

3.1 Quality Control.

(a) Quality Agreement. Intercept and PharmaZell have entered into the Quality Agreement that sets forth the terms and conditions upon which both Parties will conduct their quality activities in connection with this Agreement. Each Party shall duly and punctually perform all of its obligations under the Quality Agreement. In the event of any inconsistency between the terms of this Agreement and the terms of the Quality Agreement, the terms of the Quality Agreement shall control with respect to quality related matters, and the terms of this Agreement shall control with respect to any other matters.

(b) Materials; Vendor and Supplier Qualification and Validation. PharmaZell shall be responsible for: (i) obtaining all starting Materials (other than Intercept Materials) required to Manufacture Supplied Materials in accordance with the Specifications, Applicable Laws and cGMPs and Regulatory Documentation; and (ii) supplying all equipment and personnel necessary for the performance of the Manufacture and supply of the API to Intercept. The Quality Agreement sets forth additional details regarding each Party's obligations regarding Critical Raw Materials (as defined in the Quality Agreement) and in the qualification and validation of vendors and suppliers retained or contracted in connection with the Manufacture and any other services requested by Intercept.

(c) Analyses. PharmaZell shall be responsible for all quality control analyses of Supplied Materials and all Supplied Material shall be released by PharmaZell, in each case in accordance with the terms of the Quality Agreement.

(d) Documentation and Standard Operating Procedures. PharmaZell shall maintain complete and accurate documentation of all validation data, stability testing data, batch records, quality control, laboratory testing, complaint handling, deviations, investigations, and corrective and preventative actions and any other data required under cGMPs, Applicable Laws, and other requirements of any relevant Regulatory Authority in connection with the Manufacture of the Supplied Material. PharmaZell shall make such documentation available for inspection during any audit conducted by or on behalf of Intercept in accordance with the Quality Agreement. Throughout the term of this Agreement, and for so long thereafter as is reasonably necessary, PharmaZell shall strictly monitor and maintain records documenting its compliance with cGMPs and any other Applicable Laws, including through the establishment and implementation of such operating procedures as are reasonably necessary to assure such compliance.

(e) Inspection. The Quality Agreement sets forth each Party's rights and obligations with respect to inspection of the Supplied Material as well as inspection of the Facilities. Notwithstanding the foregoing and without limiting anything contained in the Quality Agreement, Intercept shall have the right to audit the Facilities in their entirety and inspect those portions of the Facilities and the records and information relating to the Facilities and the Manufacture of the Supplied Material, to determine and ensure that PharmaZell meets the obligations of the Quality Agreement and is compliant with the Quality Standards. PharmaZell shall permit any Regulatory Authority to audit and inspect the Facilities and the Manufacture of the Supplied Material. In connection with Intercept's determination of PharmaZell's ability to satisfy the Quality Standards pursuant to this Section 3.1(e), Intercept may, at Intercept's discretion and to the extent determined by Intercept, consult with PharmaZell regarding cGMP quality, technical capability, and performance standards. If a Regulatory Authority or Intercept identifies any observations in connection with any audit or inspection under this Section 3.1(e) or the Quality Agreement, the Parties will discuss in good faith suitable approaches for correcting such observations, and PharmaZell shall have a reasonable time following such consultation with Intercept to make appropriate corrections or dispute Intercept's observations (but not dispute a Regulatory Authority's observations which shall be deemed conclusive). If PharmaZell disputes Intercept's observations and Intercept and PharmaZell are unable to agree as to whether PharmaZell meets the Quality Standards, the Parties shall cooperate to have the Facilities and the records and information relating to the Facilities and the Manufacture of the Supplied Material inspected and audited by an independent inspection company of recognized repute selected by Intercept and approved by PharmaZell, which approval shall not be unreasonably withheld. The results of such inspection company shall be final and binding on the Parties on the issue of whether PharmaZell meets the Quality Standards.

(f) Recalls; Withdrawals. The Quality Agreement sets forth each Party's rights and obligations with respect to recalls and withdrawals. If and to the extent such recall or withdrawal is caused by Supplied Material that contains a Deficiency or by PharmaZell's negligence or willful misconduct or breach of this Agreement, PharmaZell shall reimburse Intercept for [**]; provided that, other than with respect to PharmaZell's gross negligence or willful misconduct, PharmaZell's liability pursuant to this Section 3.1(f), on a per claim basis, shall not exceed Fifteen Million United States Dollars ($15,000,000).

(g) Release. PharmaZell shall perform Release Testing to ensure conformance to the Specifications, in accordance with the Quality Agreement.

(h) Stability Testing. PharmaZell shall perform stability testing on the API to ensure conformance to the Specifications, in accordance with the Quality Agreement.

3.2 Maintenance of Facility.

(a) Except as otherwise approved in writing by Intercept, PharmaZell shall Manufacture Supplied Material exclusively at the Facilities.

(b) PharmaZell shall at all times during the Term ensure that any and all licenses, registrations, and Regulatory Authority approvals required by Applicable Law to be obtained in connection with the Facilities and their operation and equipment used or to be used in connection with the Manufacture of Supplied Material so as to permit PharmaZell to Manufacture Supplied Material and supply it to Intercept as contemplated hereunder have been obtained and are in all respects current and in full force and effect.

(c) PharmaZell shall only use disposal services or sites that have appropriate environmental permits and are in compliance with Applicable Law.

3.3 Regulatory Cooperation of PharmaZell. PharmaZell shall cooperate with any reasonable requests for assistance from Intercept with respect to obtaining, maintaining, and supporting any and all Regulatory Approvals and Regulatory Documentation required in connection with the sourcing of Supplied Material by Intercept hereunder and the sale of Products, including by:

(a) at Intercept's cost, making PharmaZell employees, consultants and other staff available upon reasonable notice during normal business hours to attend meetings with Regulatory Authorities concerning Supplied Material and Products;

(b) at PharmaZell's own cost, disclosing and making available to Intercept, in whatever form Intercept may reasonably request, all Manufacturing and quality control data, CMC Data, records, and other information related to Supplied Material, the Manufacturing process for Supplied Material, and any other services related to Supplied Material as may be reasonably necessary or desirable for Intercept to prepare, file, obtain, and maintain any Regulatory Approval required in connection with the sourcing of Supplied Material by Intercept hereunder and the sale of Products, as defined in the Quality Agreement; and

(c) to the extent that Intercept requests any additional regulatory services from PharmaZell, PharmaZell shall provide to Intercept a fee estimate for the provision of such additional regulatory services. Thereafter, the Parties shall negotiate and agree in advance on the cost and time to provide any such additional regulatory services. Intercept shall not be responsible for the cost or expense of any amount to the extent that Intercept has not explicitly agreed in writing to pay for such cost or expense.

3.4 Cooperation with Regulatory Authorities and Regulatory Correspondence.

(a) PharmaZell shall immediately notify Intercept in the event that PharmaZell receives notice from FDA or any other relevant Regulatory Authority of its intent to conduct any audit or inspection of PharmaZell with respect to the Facility or its operations, and shall cooperate with the Regulatory Authority in connection with such audit or inspection or related request, including access to records and documentation related to Manufacturing. Without limiting the foregoing, PharmaZell agrees to immediately notify Intercept of any correspondence and other documentation received or prepared by either Party in connection with any of the following events: (i) receipt of a Warning Letter, FDA Form 483, or other regulatory correspondence from the FDA or any other Regulatory Authority in connection with the manufacture or design of the API or Product; (ii) any recall of the API or Product; (iii) the mandate, advice or recommendation from any Regulatory Authority with respect to the withdrawal of any API or Product; and (d) any regulatory comments from the FDA or any other Regulatory Authority relating to the Manufacture of the Supplied Material.

(b) As applicable, PharmaZell shall provide copies of any notices or communications to Intercept of any FDA or other Regulatory Authority inspection, investigation or other inquiry, or other material governmental notice or communication, relating to the Manufacturing, or Supplied Material. PharmaZell shall consult with Intercept prior to submitting responses to any inquiry posed by any Regulatory Authority relating to the Manufacturing, Supplied Material or Product. PharmaZell shall not initiate communication with any Regulatory Authority concerning the Manufacturing, or Supplied Material absent the prior written, express permission of Intercept concerning any such communications.

3.5 Compliance with Applicable Law. With respect to the Manufacturing of Supplied Material and PharmaZell's other duties and obligations under this Agreement, PharmaZell shall strictly comply with (i) the Specifications, (ii) GMP, and all other Applicable Laws, including those relating to the processing, manufacturing, packaging, labeling, testing, inspection, storage, delivery, shipment, or disposal of the Supplied Material; (iii) the Quality Agreement; and (iv) all Applicable Laws concerning environmental matters, public health, wages, hours and conditions of employment, subcontractor selection, discrimination and occupational health/safety. Without limiting the foregoing, PharmaZell covenants that neither PharmaZell nor any of its permitted subcontractors shall utilize child, or any form of forced or involuntary, labor in the Manufacture of Supplied Material under this Agreement or source Materials from any supplier that uses child, or any form of forced or involuntary, labor. Upon Intercept's request, PharmaZell shall certify in writing its compliance with this Section 3.5 and shall provide to Intercept true and correct copies of all permits, certificates and licenses that may be required for its performance under this Agreement and, upon Intercept's request, permit Intercept to inspect originals of the same.

3.6 Change Requests.

(a) Changes Requested by Intercept. Intercept shall have the right to request an amendment, change or supplement to any of the following upon written notice to PharmaZell, and except as may be prohibited by Applicable Law, PharmaZell shall use its commercially reasonable efforts to promptly implement such change: (a) the Specifications, (b) the Materials, (c) the source of Materials, (d) the specifications for Materials, (e) the equipment used in Manufacture, (f) the test methods used in connection with the Manufacturing of Supplied Material and Materials, (g) the process for Manufacturing Supplied Material, or (h) any test methods to Manufacture or release Supplied Material. PharmaZell shall ensure that any change in any of the foregoing shall, in each case, comply with cGMPs and all Applicable Laws. PharmaZell and Intercept will jointly discuss the cost resulting from such changes.

(b) Required Manufacturing Changes. Each Party shall give the other Party reasonable written notice prior to any changes to the Specifications, process of Manufacturing, or other change, as applicable, with respect to the Supplied Materials, in each case that are required by cGMPs or Applicable Laws or a Regulatory Authority (collectively, "**Required Manufacturing Changes**"). PharmaZell shall use commercially reasonable efforts to promptly implement such Required Manufacturing Changes. PharmaZell shall ensure that any change in any of the foregoing shall, in each case, comply with cGMPs and all Applicable Laws. PharmaZell and Intercept will jointly discuss the cost resulting from such changes.

3.7 General Cooperation. PharmaZell shall cooperate with any reasonable requests for assistance from Intercept and collaborate with Intercept with respect to any responses by Intercept to any Regulatory Authority and requests for information from Regulatory Authorities, pharmacovigilance and recall matters, and in accommodating Intercept's needs for Supplied Materials, including accepting changes in forecasting and Work Orders.

ARTICLE 4
FINANCIALS

4.1 Price.

(a) Subject to Section 4.4, the purchase price (the "**Purchase Price**") for Supplied Material shall be determined as follows:

Amount of Supplied Material Ordered for Delivery in a Calendar Year	Price
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

(b) For purposes of determining the Purchase Price applicable to a given quantity of Supplied Material that is ordered for delivery for a given Calendar Year, any quantity of Supplied Material that has been ordered by Intercept for delivery in a given Calendar Year shall be deemed ordered for delivery for such Calendar Year even if such quantity is ordered or Manufactured in an earlier Calendar Year. If Intercept places multiple orders for delivery in the same Calendar Year, such that the total amount of Supplied Material ordered for delivery in such Calendar Year in the aggregate is in a higher tier than a previously placed order, the Parties shall reconcile the total amount ordered for delivery in such Calendar Year and recalculate the Purchase Price and PharmaZell shall pay to Intercept the difference or, to the extent the final invoice for such Calendar Year has not yet been paid, Intercept may reduce the amount of such invoice accordingly. For example, and by way of illustration purposes only, if Intercept places an order for [**].

4.2 Invoice and Payment. PharmaZell shall invoice Intercept for the Manufacture of Supplied Material as follows:

(a) PharmaZell shall be entitled to invoice Intercept for a certain percentage of the total Purchase Price calculated in accordance with Section 4.1(a) in accordance with the Work Order for such Supplied Material prior to delivery of the Supplied Material upon achievement of certain steps of the Manufacturing process as follows:

Milestone	Step of Manufacturing Process	Percentage of total Purchase Price
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

(b) Prior to PharmaZell issuing an invoice to Intercept pursuant to Section 4.2(a), PharmaZell shall provide to Intercept the batch documentation and the testing and analytical data, if applicable, for such step of the Manufacturing to demonstrate to Intercept that PharmaZell has successfully completed such step of the Manufacturing. Upon Intercept's acceptance of the batch documentation and the testing and analytical data, if applicable, but no later than [**] days after PharmaZell has provided such batch documentation, PharmaZell shall invoice Intercept for the percentage of the total Purchase Price for such step of the Manufacturing in accordance with Section 4.2(a) and payment shall be due [**] days after receipt of such invoice by Intercept.

(c) PharmaZell promptly shall invoice Intercept for the remaining amount of the total Purchase Price calculated pursuant to Section 4.1 for the quantities of API actually delivered (subject to Section 2.7(f)) to Intercept; provided that if the total quantity of API actually delivered is less than [**] of the total quantity ordered for delivery, PharmaZell shall reimburse Intercept for the amounts overpaid pursuant to Section 4.2(a) and the amount actually delivered. Payment for the remaining amount of the total Purchase Price for the quantity of Supplied Material actually delivered shall be due [**] days after receipt by Intercept of the invoice and receipt of corresponding Supplied Material with respect thereto (which shall be sent in electronic form contemporaneously with such delivery); provided that if Intercept rejects such Supplied Material, then payment shall be due within [**] days after receipt by Intercept of notice from the Testing Laboratory that the invoiced Supplied Material does not contain a Deficiency or receipt by Intercept of replacement Supplied Material, as the case may be. If the Supplied Material contains a Deficiency and Intercept does not order replacement Supplied Material, PharmaZell shall promptly reimburse all amounts previously paid by Intercept for such Supplied Material pursuant to Section 4.2(b).

(d) If Intercept disputes any portion of an invoice, it shall pay the undisputed portion and shall provide PharmaZell with written notice of the disputed portion and its reasons therefor, and Intercept shall not be obligated to pay such disputed portion. The Parties shall use good faith efforts to resolve any such disputes promptly. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control. Payment of invoices shall be made by wire transfer to an account designated in writing by PharmaZell.

4.3 Currency. PharmaZell will invoice Intercept in [**] and Intercept will pay in [**]. The exchange rate of [**] to [**] at the date of the last signature to this Agreement will be used as Reference Exchange Rate. Should at any time during the Agreement for a period longer than [**] months the then current exchange rate of [**] to [**] deviates more than [**] from the Reference Exchange Rate, both Parties will discuss in good faith impact on Prices and cost and adjust Price as agreed by the Parties in writing.

4.4 Adjustment of Purchase Price.

(a) The Purchase Prices set forth in Section 4.1 for Supplied Material shall remain fixed until [**] (the "**Adjustment Date**"). Effective on [**], the Purchase Price for such Supplied Material shall be adjusted by [**].

(b) If at any time market conditions (raw material costs e.g.) result in PharmaZell's cost of components for the API or manufacturing process being materially greater [**] than normal forecasted increases, then PharmaZell shall be entitled to request an adjustment to the pricing of the Supplied Material to compensate for such increased cost. The Parties shall negotiate in good faith such increase.

(c) If at any time market conditions result in PharmaZell's cost of components for the Supplied Material or manufacturing process being materially less [**] than normal, then Intercept shall be notified and an adjustment to the pricing will be given to compensate for such decreased cost.

(d) The Parties agree to make reasonable efforts to improve the productivity, efficiency and quality of the process under which the Supplied Material is Manufactured. Any investment and/or cost savings as a result of such improvement shall be shared equitably between the Parties.

4.5 Audit; Late Payments.

(a) Intercept shall have the right to have an independent accounting firm of internationally recognized standing, and reasonably acceptable to PharmaZell, provided with access by PharmaZell during normal business hours, and upon reasonable prior written notice, to examine only those records of PharmaZell (and its Affiliates) as may be reasonably necessary to determine, with respect to any Calendar Year ending not more than [**] prior to Intercept's request, the correctness of any statement submitted by PharmaZell under this Agreement. Such examinations may not (i) be conducted more than once in any [**] period (unless a previous audit during such [**] period revealed an incorrect statement submitted by PharmaZell in respect of such period or PharmaZell restates or revises its books and records for such period) or (ii) be repeated for any Calendar Year. Results of such audit shall (i) be (A) limited to information relating to the supply of Supplied Material hereunder and use of the Intercept Materials, (B) made available to both Parties in writing, and (C) subject to ARTICLE 7 and (ii) not reveal any specific information of PharmaZell to Intercept other than (A) whether statements submitted by PharmaZell under this Agreement are true and correct and (B) the amount of any excess payment reimbursable to Intercept. The cost of any such examination shall be borne by Intercept unless the examination reveals a variance of more than [**] from the amounts reflected on PharmaZell's statements, in which case PharmaZell shall bear the cost of the audit. Unless disputed pursuant to Section 4.5(c), if such audit concludes that excess payments were made by Intercept during such period, PharmaZell shall reimburse such amounts, with interest from the date originally due as provided in Section 4.5(d), within [**] days after the date on which such auditor's written report is delivered to the Parties.

(b) Solely for the purposes of ensuring Intercept's compliance with Section 2.2(b), PharmaZell shall have the right to have an independent accounting firm of internationally recognized standing, approved by Intercept, during normal business hours, and upon reasonable prior written notice which notice shall be at least [**] days prior to the audit, to examine only those records of Intercept (and its Affiliates) as may be necessary to determine whether Intercept has met its Minimum Percentage Requirement, with respect to any Calendar Year ending not more than [**] prior to PharmaZell's request. Such examinations may not be conducted more than once in any [**] period. The results communicated to Pharmazell regarding any such audit shall be limited solely to whether Intercept ordered the Minimum Percentage Requirement for such Calendar Year and any deviations from the Minimum Percentage Requirement. No other information may be included in the audit results and the audit results must be concurrently communicated to Intercept in writing. The cost of any such examination shall be borne by PharmaZell. Unless disputed pursuant to Section 4.5(c), if such audit concludes that Intercept did not order the Minimum Percentage Requirement for such Calendar Year, Intercept shall order an additional amount of Supplied Material in a subsequent calendar year equal to the difference between the amount of Supplied Material Intercept actually ordered from PharmaZell in such Calendar Year and the amount Intercept would have ordered had Intercept actually ordered the Minimum Percentage Requirement for such Calendar Year.

(c) In the event of a dispute of any examination conducted under Section 4.5, PharmaZell and Intercept shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [**] days, the dispute shall be resolved in accordance with Section 10.7.

(d) If any undisputed payment due to a Party under this Agreement is not paid when due, then the owing Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) equal to the lesser of [**], and [**]. Interest payable under this Section 4.5(d) shall run from the date upon which payment of the relevant undisputed principal sum became due through the date of payment thereof in full together with such interest.

ARTICLE 5
INTELLECTUAL PROPERTY

5.1 Ownership of Inventions.

(a) Intercept shall own all right, title and interest in and to (i) the Specifications and the Intercept Information, (ii) any and all Specified Inventions, (iii) the API and the API Precursor, and (iv) any and all work outputs and reports prepared by PharmaZell (together, "**Intercept Intellectual Property**"). PharmaZell shall, and shall cause its Affiliates to, promptly disclose in writing to Intercept the discovery, development, making, conception or reduction to practice of any Specified Invention and does hereby, and shall cause its Affiliates, employees, agents, subcontractors to, assign to Intercept any and all right, title or interest PharmaZell or its Affiliates may have in or to any Specified Invention. Intercept shall, and does hereby, grant to PharmaZell and its Affiliates a non-exclusive, royalty-free license to use the Specifications, Intercept Information, Specified Inventions, and Specified Invention Patents for the sole purpose of performing PharmaZell's obligations hereunder. The Specified Inventions and the work outputs and reports shall be considered Intercept Information.

(b) PharmaZell shall keep complete, accurate and dated records of the results of the services performed under this Agreement and all Specified Inventions and will promptly and fully disclose to Intercept such results and Specified Inventions. Such records shall also identify the names of PharmaZell's employees, officers or Affiliates who performed the work. Intercept may discuss, in person or otherwise, the services and the results thereof from time to time with PharmaZell and such employees. PharmaZell agrees that it shall not publish or present any information related to the Intercept Information, the Product, API or the results thereof, any Specified Inventions or any other Intercept Intellectual Property without the prior written consent of Intercept unless PharmaZell is legally obliged to do so. PharmaZell must identify and obtain Intercept's approval prior to inclusion of any PharmaZell technology into any Supplied Material or other deliverable hereunder.

(c) PharmaZell shall own all right, title and interest in and to any and all Other PharmaZell Inventions. PharmaZell shall, and shall cause its Affiliates to, promptly disclose in writing to Intercept the discovery, development, making, conception or reduction to practice of any Other PharmaZell Invention. PharmaZell shall, and does hereby, grant to Intercept a non-exclusive, royalty-free, irrevocable and transferable license to Other PharmaZell Inventions and Other PharmaZell Invention Patents and, to any PharmaZell technology to the extent it is incorporated into or otherwise necessary to Manufacture or use API (including any Intermediary incorporated therein), with the right to sublicense through multiple tiers, to Exploit API and Products (and any Intermediary incorporated therein) in all fields of use in all countries worldwide.

(d) PharmaZell and Intercept shall jointly own all right, title and interest in and to any and all Joint Inventions. Each of PharmaZell and Intercept shall, and shall cause its respective Affiliates to, promptly disclose in writing to the other Party the discovery, development, making, conception or reduction to practice of any Joint Invention. For those countries worldwide where a specific license is required to be granted by a Joint Invention owner to the other Joint Invention owner in order for the other Joint Invention owner to practice such Joint Inventions in such country, (i) PharmaZell shall, and does hereby, grant to Intercept a non-exclusive, royalty-free, irrevocable, transferable license, with the right to sublicense through multiple tiers, to PharmaZell's interest in all Joint Inventions and Joint Invention Patents in all fields of use and (ii) Intercept shall, and does hereby, grant to PharmaZell a non-exclusive, royalty-free, irrevocable license, with the right to sublicense through multiple tiers, to Intercept 's interest in all Joint Inventions and Joint Invention Patents in all fields of use.

(e) Without limiting the provisions of this Section 5.1, PharmaZell shall use the Specifications and Intercept Information solely for purposes of performing its obligations hereunder.

(f) Upon the request and at the expense of Intercept, PharmaZell shall execute and deliver any and all instruments and documents and take such other acts as may be necessary or desirable to document the assignment and transfer described in Section 5.1(a) or to enable Intercept to secure its rights in the Specified Invention and Specified Invention Patents relating thereto in any and all jurisdictions, or to apply for, prosecute and enforce Specified Invention Patents, or to obtain any extension, validation, re-issue, continuance or renewal of any such Specified Invention Patents. Without limiting the foregoing, PharmaZell shall disclose to Intercept all pertinent information and data with respect thereto and shall execute all applications, specifications, oaths and all other instruments which Intercept deems necessary in order to apply for and obtain such rights and in order to assign and convey to Intercept the sole and exclusive right, title and interest in and to such Specified Invention Patents relating thereto. If Intercept is unable for any other reason to secure PharmaZell's signature to apply for or to pursue any application for any United States or foreign patent, trademark, copyright or other registration covering Inventions assigned to Intercept hereunder, then PharmaZell hereby irrevocably designates and appoints Intercept and its duly authorized officers and agents as PharmaZell's agent and attorney in fact, to act for and in PharmaZell's behalf and instead to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of letters patent or trademark, copyright or other registrations thereon with the same legal force and effect as if executed by PharmaZell.

(g) Inventorship Acts. To the extent applicable, the Parties understand that Inventions that are conceived, developed, generated or reduced to practice under this Agreement may be subject to the German Act on Employee Inventions (the German "**Gesetz über Arbeitnehmererfindungen**"). The provisions of such Gesetz über Arbeitnehmererfindungen are, inter alia, designed to protect the rights of employees to so called employee inventions (the "**Employee Inventions**"); the provisions of the Gesetz über Arbeitnehmererfindungen constitute inalienable rights which may not be changed by contractual arrangements to the detriment of the employees. To the extent that Inventions relate to Employee Inventions under the German Gesetz über Arbeitnehmererfindungen made by employees of a Party or its Affiliates, such Party undertakes to claim the rights in and to such Employee Inventions under Section 5ss. of the Gesetz über Arbeitnehmererfindungen. To the extent that such Party acquires rights to Employee Inventions in accordance with the principles stated in this Section 5.1(g), the further provisions of this 5.1 shall apply to such Inventions. The Party subject to the Gesetz über Arbeitnehmererfindungen shall be solely responsible for any payments to its employees and such Party will take all actions necessary to obtain the rights to use any such Inventions for the other Party. In addition, PharmaZell shall comply with all other inventorship laws of a country in which any portion of a Supplied Material is Manufactured.

5.2 Patent Prosecution.

(a) Specified Invention Patents.

(i) Intercept shall have sole discretion and responsibility to prepare, file, prosecute and maintain all patent applications and patents covering Specified Inventions (the "**Specified Invention Patents**") and shall be responsible for related interference and opposition proceedings. PharmaZell shall have no right to prepare, file, prosecute or maintain any Specified Invention Patents.

(ii) Costs and expenses of filing, prosecuting and maintaining (including any costs and expenses of patent interference, opposition, reissue, re-examination, and post-grant procedure proceedings) Specified Invention Patents shall be borne by Intercept.

(b) Other PharmaZell Invention Patents.

(i) PharmaZell shall have the first right, but not the obligation, to prepare, file, prosecute and maintain all patent applications and patents covering Other PharmaZell Inventions (the "**Other PharmaZell Invention Patents**") and shall be responsible for related interference and opposition proceedings; provided, however, that if PharmaZell plans to abandon any Other PharmaZell Invention Patent, PharmaZell shall notify Intercept in writing at least [**] days in advance of the due date of any payment or other administrative action that is required to maintain such Other PharmaZell Invention Patent (i.e., an administrative action that involves routine and customary filings, it being understood that interference, opposition, reissue, re-examination, and post-grant procedure proceedings, prosecution or defense of infringement actions, and the like, shall not be considered administrative actions), and Intercept may elect, upon written notice within such [**]-day period to PharmaZell, to make such payment or take such administrative action on behalf of PharmaZell. Except as expressly permitted in this Section 5.2(b)(i), Intercept shall have no right to prepare, file, prosecute or maintain any Other PharmaZell Invention Patents.

(ii) If PharmaZell does not wish to file, prosecute or maintain any Other PharmaZell Invention Patent or maintain or defend any Other PharmaZell Invention Patent in a particular country, it shall notify Intercept in writing and, if Intercept elects to maintain such Other PharmaZell Invention Patent as contemplated by Section 5.2(b)(i), PharmaZell shall, and shall cause its Affiliates, as applicable, to (A) reasonably cooperate with Intercept in this regard and, (B) upon Intercept's request, promptly release or assign to Intercept, without compensation, all right, title and interest in and to such Other PharmaZell Invention Patent in such country. In the event of such assignment, Intercept hereby grants to PharmaZell a non-exclusive, royalty-free, irrevocable license, with the right to sublicense through multiple tiers, under the relevant Other PharmaZell Invention Patent in all fields of use in the relevant country.

(iii) Costs and expenses of filing, prosecuting and maintaining (including any costs and expenses of patent interference, opposition, reissue, re-examination, and post-grant procedure proceedings) Other PharmaZell Invention Patents as contemplated by this Section 5.2(b) shall be borne by the Party controlling such filing, prosecution and maintenance.

(c) Joint Invention Patents.

(i) Intercept shall have the first right, but not the obligation, to prepare, file, prosecute and maintain all patent applications and patents covering Joint Inventions (the "**Joint Invention Patents**") and shall be responsible for related interference and opposition proceedings; provided, however, that if Intercept plans to abandon any Joint Invention Patent, Intercept shall notify PharmaZell in writing at least [**] days in advance of the due date of any payment or other administrative action that is required to maintain such Joint Invention Patent (i.e., an administrative action that involves routine and customary filings, it being understood that interference, opposition, reissue, re-examination, and post-grant procedure proceedings, prosecution or defense of infringement actions, and the like, shall not be considered administrative actions), and PharmaZell may elect, upon written notice within such [**]-day period to Intercept, to make such payment or take such administrative action on behalf of Intercept. Except as expressly permitted in this Section 5.2(c)(i), PharmaZell shall have no right to prepare, file, prosecute or maintain any Joint Invention Patents.

(ii) If Intercept does not wish to file, prosecute or maintain any Joint Invention Patent or maintain or defend any such Joint Invention Patent in a particular country, it shall notify PharmaZell in writing and, if PharmaZell elects to maintain such Joint Invention Patent as contemplated by Section 5.2(c)(i), Intercept shall, and shall cause its Affiliates, as applicable, to reasonably cooperate with PharmaZell in this regard.

(iii) Costs and expenses of filing, prosecuting and maintaining (including any costs and expenses of patent interference, opposition, reissue, re-examination, and post-grant procedure proceedings) Joint Invention Patents as contemplated by this Section 5.2(c) shall be borne by the Party controlling such filing, prosecution and maintenance.

(d) Each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its activities set forth in this Section 5.2.

(i) Each Party shall keep the other Party currently informed of all steps to be taken in the preparation and prosecution of all applications filed by it according to Sections 5.2(b) and 5.2(c) and shall furnish such other Party with copies of such applications for patents, amendments thereto and other related correspondence to and from patent offices, and, to the extent reasonably practicable, permit such other Party an opportunity to offer its comments thereon before making a submission to a patent office which could materially affect the scope or validity of the patent coverage that may result. Such other Party shall offer its comments, if any, promptly.

5.3 Enforcement of Patents.

(a) If any Specified Invention Patent, Other PharmaZell Invention Patent, or Joint Invention Patent is allegedly or actually infringed by any Person, the Party first having knowledge of such infringement shall promptly notify the other in writing. The notice shall set forth the facts of that infringement in reasonable detail.

(b) As between the Parties, Intercept shall have the sole and exclusive right, but not the obligation, to prosecute any infringement described in Section 5.3(a). To the extent any such action relates to an Other PharmaZell Invention Patent or a Joint Invention Patent, PharmaZell shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(c) PharmaZell shall cooperate fully, including furnishing of a power of attorney, being joined as a party plaintiff or indispensable party in such action, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours in connection with any enforcement action that may be brought by Intercept under this Section 5.3.

(d) Any costs and expenses relating to any enforcement action commenced by Intercept pursuant to this Section 5.3 shall be borne by Intercept and any damages or other amounts collected in any such enforcement action shall be retained by Intercept.

5.4 Third Party Litigation.

(a) If any Person institutes against PharmaZell any action that alleges that the Manufacture of Supplied Material hereunder in accordance with the terms hereof infringes the intellectual property rights held by such Person, then, as between PharmaZell and Intercept, Intercept shall have the first right, but not the obligation, to contest, and assume direction and control of the defense of, such action, including the right to settle such action; provided that, prior to any such settlement, PharmaZell provides its written consent (such consent not to be unreasonably withheld, conditioned or delayed). If Intercept determines not to defend against such action, then PharmaZell shall, at its sole cost and expense, have the right but not the obligation to control the defense of such action except to the extent it relates to a Specified Invention Patent; provided that, if an Other PharmaZell Invention Patent or Joint Invention Patent is at issue in the action and is the only patent protecting a Product, then PharmaZell shall in any event consult with Intercept with respect to any such action and shall obtain Intercept's written consent prior to taking any steps in respect of such action. Intercept shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(b) Any costs and expenses relating to any defense undertaken pursuant to this Section 5.4 shall be borne by the Party controlling the defense. Any damages or other amounts recovered shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Party that has exercised its right to control the defense of the action.

(c) In the event that a Party entitled to defend an infringement action does so in accordance with this Section 5.4, the other Party shall cooperate fully, including providing access to relevant documents and other evidence and making its employees available at reasonable business hours. If a Party pursues the defense of such an infringement action, it shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken to remedy such infringement.

5.5 Third Party Licenses. If, in the absence of a license from a Person, the Manufacture of API or API Precursor hereunder in accordance with the terms hereof infringes or misappropriates any patent or any intellectual property right of such Person, such that PharmaZell or any of its Affiliates cannot Manufacture the API or API Precursor without infringing the patent or intellectual property rights of such Person, then Intercept shall have the sole and exclusive right to take the lead in negotiating the terms of any such license. The Parties shall negotiate in good faith an appropriate allocation of any royalties or other payments to be made pursuant to any such license so as to reflect the economic interests of the Parties under this Agreement with respect to the Product.

5.6 United States Law. The determination of whether Inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States. In the event that United States law does not apply to the creation, conception, discovery, development or making of any Invention hereunder, each Party shall, and does hereby, assign, and shall cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Inventions, as well as any intellectual property rights with respect thereto, as necessary to fully effect ownership as contemplated by Section 5.1 and the preceding sentence of this Section 5.6.

ARTICLE 6
REPRESENTATIONS AND WARRANTIES; COVENANTS

6.1 Representations and Warranties of Each Party. Each Party hereby represents and warrants to the other Party as of the Effective Date, and covenants with the other Party, as follows:

(a) Such Party (i) is duly formed and in good standing under the laws of the jurisdiction of its formation, (ii) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (iii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered in a proceeding at law or equity;

(b) All necessary consents, approvals and authorizations of all Regulatory Authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained; and

(c) The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not and will not conflict with or violate any requirement of Applicable Law or any provision of the articles of incorporation, bylaws, limited partnership agreement or other similar documents of such Party and (ii) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

6.2 Additional Representations, Warranties and Covenants of PharmaZell. PharmaZell hereby represents and warrants to Intercept as of the Effective Date, and covenants to Intercept, as follows:

(a) PharmaZell has executed agreements with all Affiliates, employees, agents subcontractors and any other representative of PharmaZell performing services for PharmaZell in connection with the Manufacture and supply of Supplied Materials to Intercept, or its designee (each, a "**Representative**") requiring such Representative to assign all right, title and interest in and to any intellectual property conceived, discovered, developed or otherwise made by such Representative to PharmaZell;

(b) In connection with each delivery, and as of the date of delivery, of Supplied Materials to Intercept or its designee: (i) such Supplied Material has been Manufactured in compliance with the Specifications and is in conformity with the Specifications, the Certificate of Analysis and the Certificate of Conformance therefor provided pursuant to Section 2.3(b); (ii) such Supplied Material has been Manufactured, stored, disposed of and handled in conformance with GMP, all other Applicable Laws, the Regulatory Documentation and Regulatory Approvals, this Agreement and the Quality Agreement; (iii) title to such Supplied Material will pass to Intercept free and clear of any security interest, lien or other encumbrance; (iv) the Facilities are in compliance with all Applicable Law at the time of such Manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities); (v) the retest date of such Supplied Material meets the retest set forth in the Specifications or otherwise determined in accordance with Applicable Law after the date of delivery thereof for such Supplied Material; and (vi) such Supplied Material has not been adulterated or misbranded within the meaning of the FFDCA or other Applicable Law, or is an article that may not, under the FFDCA or other Applicable Law, be introduced into interstate commerce (collectively, the "**Supplied Material Warranty**");

(c) neither PharmaZell nor any of its Affiliates, nor any Third Party engaged by PharmaZell has ever been, are currently, nor during the performance of any services hereunder, shall become: (i) disqualified or debarred by the FDA or other Regulatory Authorities for any purpose pursuant to Applicable Laws (including United States law, including the statutory debarment provisions at 21 U.S.C. § 335a(a) or (b)) or is under consideration or investigation to be disqualified or debarred, or has been convicted of, or is currently charged with, a felony for conduct relating to the development, approval, regulation or handing of any drug product under any Applicable Law; (ii) charged or convicted for conduct relating to the development or approval of, or otherwise relating to the regulation of, any drug product under any Applicable Laws; (iii) excluded or, to the best of the knowledge of PharmaZell after due inquiry, threatened with exclusion under state or federal laws, including under 42 U.S.C. § 1320a-7 or relevant regulations in 42 C.F.R. Part 1001, or assessed or, to the best of the knowledge of PharmaZell after due inquiry, threatened with assessment of civil money penalties pursuant to 42 U.S.C. Part 1003; (iv) ineligible for contract with the federal government, including due to disbarment, disqualification, or conviction of a felony related to conduct relating to the development, approval, regulation or handing of any drug product under any Applicable Law; or (v) subject to similar actions by any state, local, or foreign governmental authority (collectively "**Disqualification**"). PharmaZell agrees to notify Intercept immediately, in the event that PharmaZell or any of its officers, directors, employees, agents, or parties under contract to perform and work under this Agreement, (i) becomes subject to Disqualification, or (ii) receives or becomes aware of an action, notice of action, inquiry, or investigation with relating to or that could result in Disqualification during the Term. In the event that PharmaZell receives any notice of actions set forth in this Section 6.2(c), without limiting any other rights or remedies of Intercept, Intercept shall have the right to terminate this Agreement immediately pursuant to the provisions of this Agreement. Any termination by Intercept pursuant to this Section 6.2(c) shall be deemed to be a termination by Intercept for material breach of this Agreement by PharmaZell;

(d) its retention as a contractor by Intercept and its Manufacture of Supplied Material do not, and shall not, breach any agreement that obligates PharmaZell to keep in confidence any trade secrets or confidential information of any third party or to refrain from competing, directly or indirectly, with the business of any other party;

(e) the Manufacture and supply of the Supplied Material shall be performed with requisite care, skill and diligence, in accordance with this Agreement, Applicable Laws and industry standards, and by individuals who are appropriately trained and qualified; and

(f) the Manufacturing services provided under this Agreement will not infringe the intellectual property rights of any third party, and PharmaZell will promptly notify Intercept in writing should it become aware of any claims asserting such infringement.

6.3 Disclaimer of Other Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF MERCHANTABILITY.

ARTICLE 7
CONFIDENTIALITY

7.1 Confidential Information. Subject to the provisions of Sections 7.2 and 7.3, at all times during the Term and for [**] following the expiration or termination of this Agreement, the Receiving Party (a) shall keep completely confidential and shall not publish or otherwise disclose any Confidential Information furnished to it by the Disclosing Party, except to those of the Receiving Party's employees, Affiliates, or consultants who have a need to know such information to perform such Party's obligations hereunder (and who shall be advised of the Receiving Party's obligations hereunder and who are bound by confidentiality obligations with respect to such Confidential Information no less onerous than those set forth in this Agreement) (collectively, "**Recipients**") and (b) shall not use Confidential Information of the Disclosing Party directly or indirectly for any purpose other than performing its obligations or exercising its rights hereunder. The Receiving Party shall be jointly and severally liable for any breach by any of its Recipients of the restrictions set forth in this Agreement. Notwithstanding the foregoing, trade secrets of the Disclosing Party shall be maintained by the Receiving Party for so long as such information remains the trade secret of the Disclosing Party.

7.2 Exceptions to Confidentiality. The Receiving Party's obligations set forth in this Agreement shall not extend to any Confidential Information of the Disclosing Party:

(a) that is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of a Receiving Party or its Recipients;

(b) that is received from a third party without restriction and without breach of any agreement between such third party and the Disclosing Party;

(c) that the Receiving Party can demonstrate by competent evidence was already in its possession without any limitation on use or disclosure prior to its receipt from the Disclosing Party;

(d) that is generally made available to third parties by the Disclosing Party without restriction on disclosure; or

(e) that the Receiving Party can demonstrate by competent, written evidence was independently developed by the Receiving Party without the use of the Disclosing Party's Confidential Information.

7.3 Disclosure. Each Party may disclose Confidential Information to the extent that such disclosure is:

(a) made in response to a valid order of a court of competent jurisdiction or other Regulatory Authority of a country or any political subdivision thereof of competent jurisdiction; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order requiring that the Confidential Information or documents that are the subject of such order be held in confidence by such court or governmental body or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information that is legally required to be disclosed in such response to such court or governmental order;

(b) otherwise required by law or regulation, in the reasonable opinion of legal counsel for the Receiving Party; provided, however, the Receiving Party must promptly give the Disclosing Party notice of any such disclosure and provide the Disclosing Party with reasonable assistance in obtaining a protective order with respect to the Confidential Information subject to disclosure;

(c) Intercept may disclose Confidential Information to the extent that such disclosure is made to Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information; or

(d) To the extent, if any, that a Party concludes in good faith that it is required by applicable laws or regulations to file or register this Agreement or a notification thereof with any Regulatory Authority, including the U.S. Securities and Exchange Commission, such Party may do so, and the other Party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith. In such situation, the filing Party shall request confidential treatment of sensitive provisions of the Agreement, to the extent permitted by Applicable Law and in consultation with the other Party. The Parties shall promptly inform each other as to the activities or inquiries of any such Regulatory Authority relating to this Agreement, and shall cooperate to respond to any request for further information therefrom.

7.4 Notification. The Receiving Party shall notify the Disclosing Party immediately, and cooperate with the Disclosing Party as the Disclosing Party may reasonably request, upon the Receiving Party's discovery of any loss or compromise of the Disclosing Party's Confidential Information.

7.5 Remedies. Each Party agrees that the unauthorized use or disclosure of any information by the Receiving Party in violation of this Agreement will cause severe and irreparable damage to the Disclosing Party. In the event of any violation of this ARTICLE 7, the Receiving Party agrees that the Disclosing Party shall be authorized and entitled to seek to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, as well as any other relief permitted by Applicable Law. The Receiving Party agrees to waive any requirement that the Disclosing Party post bond as a condition for obtaining any such relief.

7.6 Use of Names. Neither Party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 7.6 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information.

7.7 Press Releases. Except as expressly provided in Section 7.3, neither Party shall make a press release or other public announcement regarding this Agreement, the terms hereof or the transactions contemplated hereby without the prior written approval of the other Party. Each Party shall provide the other with the proposed text of any such press release or public announcement for review and approval, which approval shall not be unreasonably withheld, conditioned or delayed, as early as possible, but in no event less than [**] Business Days in advance of the publication, communication or dissemination thereof; provided, however, that the receiving Party shall be deemed to have approved any such press release or public announcement if it fails to notify the proposing Party in writing of any objections to such press release or public announcement within [**] Business Days after receipt by the receiving Party of the text of such public announcement.

ARTICLE 8
TERM AND TERMINATION

8.1 Term. This Agreement shall commence as of the Effective Date and, unless earlier terminated in accordance with the terms hereof, shall expire on December 31, 2020 (the "**Initial Term**"). Thereafter, this Agreement shall automatically renew for successive two (2)-year periods (each a "**Renewal Period**") unless (a) Intercept provides notice to PharmaZell indicating its desire not to renew at least twelve (12) months prior to the end of the Initial Term or then-current Renewal Period, as applicable, or (b) PharmaZell provides notice to Intercept indicating its desire not to renew at least twelve (12) months prior to the end of the Initial Term or then-current Renewal Period, as applicable. The Initial Term together with any Renewal Periods, shall be the "**Term**".

8.2 Termination. In addition to any other provision of this Agreement expressly providing for termination of this Agreement, this Agreement may be terminated as follows:

(a) Intercept may terminate this Agreement immediately upon written notice to PharmaZell in the event that (i) Regulatory Authorities require or cause the withdrawal of Product or if the Product is not approved by the FDA and the European Medicines Agency (EMA) or (ii) [**].

(b) Intercept may terminate this Agreement immediately upon written notice to PharmaZell if (i) PharmaZell does not deliver at least [**] of the amount of Supplied Material specified in a Work Order within [**] of the Delivery Date specified in such Work Order or (ii) PharmaZell does not deliver at least [**] of Supplied Material in [**] provided that Intercept has ordered at least [**] of Supplied Product for delivery in [**].

(c) This Agreement may be terminated by either Party:

(i) immediately upon written notice if the other Party shall (A) file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction a petition in bankruptcy or insolvency or for reorganization or for arrangement or for the appointment of a receiver or trustee of that Party or of its assets, (B) propose a written agreement of composition or extension of its debts, (C) be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within [**] days after the filing thereof, (D) propose or be a party to any dissolution or liquidation, (E) make an assignment for the benefit of its creditors, or (F) admit in writing its inability generally to pay its debts as they fall due in the general course;

(ii) immediately upon written notice in the event of any material breach by the other Party in the performance of any of its obligations herein contained that (if curable) has not been cured by the defaulting Party within [**] days after receiving written notice thereof from the non-breaching Party;

(iii) immediately upon written notice in the event that, as a result of an order of government or any other official authority, the continued operation of this Agreement in its entirety or in substantial part is prohibited or prevented or delayed for an unspecified and indeterminate period; or

(iv) as provided in Section 10.2.

(d) Intercept may terminate this Agreement immediately upon written notice to PharmaZell in the event that (i) any audit by a Regulatory Authority identifies critical or major finding (as defined by the FDA and/or EMA) at a Facility and such critical or major finding is not remedied by PharmaZell within the time period as agreed between the Regulatory Authorities and PharmaZell or as mandated by the Regulatory Authorities after the identification thereof, (ii) PharmaZell fails to meet and/or maintain the Quality Standards and does not remedy such failure within a reasonable time as agreed between Intercept and PharmaZell or, if no agreement is reached with respect to such time, such time as established by an independent auditor, or (iii) any audit reveals that a Facility is in violation of Applicable Laws.

8.3 Effect of Expiration or Termination.

(a) The expiration or earlier termination of this Agreement shall be without prejudice to any rights or obligations of the Parties that may have accrued prior to such termination. Those provisions that by their terms or intent are required to survive the expiration or earlier termination of the Agreement in order to give effect to the intent of the Parties shall so survive. Without limiting the foregoing, the provisions of Sections 4.5, 6.3 and 8.3 and ARTICLE 5, ARTICLE 7, ARTICLE 9 and ARTICLE 10 shall survive the expiration or termination of this Agreement and continue thereafter in accordance with and to the extent of their terms. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available at law or in equity.

(b) Upon expiration or earlier termination of this Agreement, each Party, at the request of the other, shall return all data, files, records and other materials in its possession or Control containing or comprising the other Party's Confidential Information except that the legal department of such Party may retain one copy solely for archival purposes.

(c) Upon any termination of this Agreement by Intercept pursuant to Section 8.2(a) or by PharmaZell pursuant to Section 8.2(c), (i) PharmaZell shall return to Intercept all Intercept Materials, (ii) Intercept shall purchase from PharmaZell the amount of Supplied Material that is subject to Work Orders outstanding at the time of such termination, (iii) Intercept shall reimburse PharmaZell for work in process and Materials that PharmaZell has purchased for the purpose of supplying Supplied Material to Intercept in accordance with the delivered Work Orders, and (iv) Intercept shall pay PharmaZell's direct cost for any such work in process in accordance with the Work Orders and PharmaZell's purchase price from its suppliers for any such Materials ordered for such Work Orders that have a minimum of [**] shelf life and have been stored and controlled by PharmaZell per the Quality Agreement; provided, however that PharmaZell shall use reasonable best efforts to return such Materials to suppliers or use such Materials in the manufacture of product for third parties. In the event of termination of this Agreement by Intercept pursuant to Section 8.2(b), 8.2(c) or 8.2(d), at the request of Intercept, PharmaZell shall fulfill all outstanding Work Orders for Supplied Materials prior to the effective date of such termination and to the extent not used to fulfill Work Orders at Intercept's request, PharmaZell shall return to Intercept all Intercept Materials.

(d) Except as and to the extent contemplated by Section 8.3(c), upon expiration of this Agreement or any earlier termination of this Agreement, PharmaZell immediately shall cease all Manufacturing of Supplied Materials pursuant to this Agreement.

(e) Following expiration or termination of this Agreement, PharmaZell shall (i) provide Intercept with such reasonable cooperation and support with respect to regulatory matters as Intercept may require in order to dispose of previously purchased API, (ii) grant to Intercept a perpetual, irrevocable, non-exclusive royalty-free license (with the right to grant sublicenses) under know-how, patents and other intellectual property rights owned, licensed or otherwise controlled by PharmaZell (or any of its Affiliates) as may be necessary or useful for the purpose of making and having made the API and API Precursor and (iii) within thirty (30) days of such expiration or termination, provide to Intercept copies of the physical embodiment of those processes, protocols, procedures, methods, tests and other know-how, relating to the Manufacturing of the API and API Precursor. In addition, PharmaZell shall provide reasonable assistance to Intercept and its Affiliates with respect to assisting Intercept and its Affiliates in obtaining all necessary regulatory approvals and/or modifying existing Regulatory Approvals for the Manufacture of the API.

ARTICLE 9
INDEMNIFICATION

9.1 PharmaZell Indemnification. PharmaZell shall indemnify Intercept, its Affiliates and sublicensees and its and their respective directors, officers, employees and agents (the "**Intercept Indemnified Parties**"), and defend and hold each of them harmless, from and against any and all claims, lawsuits, actions, suits and demands brought by a third party (a "**Third Party Claim**") and all associated losses, damages, liabilities, penalties, costs and expenses (including reasonable attorneys' fees and disbursements) (collectively, "**Losses**") incurred by any of them arising from or occurring as a result of (a) the breach by PharmaZell of any of its representations or warranties set forth in this Agreement, (b) PharmaZell's breach of any of its covenants or obligations under this Agreement, (c) PharmaZell's gross negligence or willful misconduct in the performance of this Agreement, (d) the storage, release, or disposal of any hazardous or regulated material or any waste by PharmaZell, (e) violation of Applicable Law by any PharmaZell Indemnitee, or (f) the enforcement by Intercept of its rights under this Section 9.1, except, in each case, for those Losses for which Intercept has an obligation to indemnify the PharmaZell Indemnified Parties pursuant to Section 9.2, as to which Losses each Party shall indemnify the other Party to the extent of its respective liability for such Losses.

9.2 Intercept Indemnification. Intercept shall indemnify PharmaZell, its Affiliates and its and their respective directors, officers, employees and agents (the "**PharmaZell Indemnified Parties**"), and defend and hold each of them harmless, from and against any and all Third Party Claims and all associated Losses incurred by any of them arising from or occurring as a result of (a) the breach by Intercept of any of its representations or warranties set forth in this Agreement, (b) Intercept's breach of its covenants or obligations under this Agreement, (c) violation of Applicable Law by any Intercept Indemnitee, or (d) the enforcement by PharmaZell of its rights under this Section 9.2, except, in each case, for those Losses for which PharmaZell has an obligation to indemnify the Intercept Indemnified Parties pursuant to Section 9.1, as to which Losses each Party shall indemnify the other Party to the extent of its respective liability for such Losses.

9.3 Indemnification Procedure.

(a) Notice of Claim. The indemnified party (the "**Indemnified Party**") shall give the indemnifying Party (the "**Indemnifying Party**") prompt written notice (an "**Indemnification Claim Notice**") of any Third Party Claims and the associated Losses or discovery of facts upon which such Indemnified Party intends to base a request for indemnification under Section 9.1 or 9.2, but in no event shall the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses.

(b) Control of Defense. At its option, the Indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [**] days after the Indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party, which shall be reasonably acceptable to the Indemnified Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnified Party in connection with the Third Party Claim. Subject to Section 9.3(c), if the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless a Intercept Indemnified Party or PharmaZell Indemnified Party, as applicable, from and against the Third Party Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses (including reasonable attorneys' fees and costs of suit) and any Losses incurred by the Indemnifying Party in its defense of the Third Party Claim with respect to such Intercept Indemnified Party or PharmaZell Indemnified Party, as applicable.

(c) Right to Participate in Defense. Without limiting Section 9.3(b), any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the Indemnified Party's own expense unless (A) the employment thereof has been specifically authorized by the Indemnifying Party in writing, (B) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 9.3(b) (in which case the Indemnified Party shall control the defense), or (C) the interests of the Indemnified Party and the Indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under applicable law, ethical rules or equitable principles.

(d) Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim, without any admission of liability or fault, and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 9.3(b), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). The Indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim without the prior written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

(e) Cooperation. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

(f) Expenses. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a calendar quarter basis in arrears by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

9.4 Insurance.

(a) During the Term, each Party shall maintain adequate liability insurance covering its activities and obligations under this Agreement that is standard and reasonable in the biopharmaceutical industry for companies conducting similar activities; provided that for PharmaZell in no event shall such amounts be less than (i) with respect to comprehensive general liability insurance, a combined single limit for bodily injury and property damage of not less than [**] and (ii) with respect to product liability/completed operations coverage, a per claim limit of not less than [**] (collectively, the "**Policies**"). If any Policy is written on a claims-made basis, the retroactive date, if any, shall not be later than the Effective Date and such coverage shall be continued for a period of [**] following the Term. Each Party shall provide prompt notice to the other Party in the event that the first Party's Policies are canceled or subjected to a reduction of coverage or any other material adverse modification.

(b) Each Party shall furnish certificates of insurance for its Policies to the other Party within [**] days after the Effective Date.

9.5 Limitation on Damages. IN NO EVENT SHALL: (A) EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES, INCLUDING BUSINESS INTERRUPTION OR LOST PROFITS, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE AND (B) EITHER PARTY'S LIABILITY EXCEED FIFTEEN MILLION UNITED STATES DOLLARS ($15,000,000) ON A PER CLAIM BASIS. THE FOREGOING LIMITATIONS AND EXCLUSIONS ARE NOT INTENDED TO, NOR SHALL THEY, EXCLUDE OR LIMIT DAMAGES OR CLAIMS CAUSED BY A PARTY'S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR BREACH OF THE PROVISIONS OF ARTICLE 5, OR EXCLUDE OR LIMIT A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 9.1 OR 9.2.

ARTICLE 10
MISCELLANEOUS

10.1 Notices. All notices, requests and other communications hereunder must be in writing, specifically reference this Agreement in a prominent manner, and be delivered personally, sent by first class registered or certified mail, postage prepaid, return receipt requested or by internationally recognized overnight delivery service that maintains records of delivery to the Parties at the following addresses:

If to Intercept to:

Intercept Pharma Europe Ltd.
2 Pancras Square, Floor 1, London
United Kingdom N1C 4AG
Attention: [**]

with copies (which shall not constitute notice) to:

Intercept Pharma Europe Ltd.
2 Pancras Square, Floor 1, London
United Kingdom N1C 4AG
Attention: Head of Legal

and

Intercept Pharmaceuticals, Inc.
450 W 15th St,
Suite 505 Floor 5
New York, NY 10011
Attention: General Counsel

If to PharmaZell to:

PharmaZell GmbH
Rosenheimer Straβe 43
83064 Raubling
Germany
Attention: [**]

All such notices, requests and other communications will (a) if delivered personally to the address as provided in this Section, be deemed given upon delivery, (b) if delivered by internationally recognized overnight delivery courier be deemed given on the second Business Day (at the place of delivery) after deposit with such internationally recognized delivery service, (c) if sent by first class registered or certified mail, postage prepaid, return receipt requested, within the United States, on the third Business Day following the date of mailing, and (d) if sent by international first class registered or certified mail, postage prepaid, return receipt requested, on the seventh Business Day following the date of mailing. Any Party from time to time may change its address or other information for the purpose of notices to that Party by giving notice specifying such change to the other Party hereto.

10.2 Force Majeure. Neither Party shall be liable for delay in delivery or nonperformance in whole or in part, nor shall the other Party have the right to terminate this Agreement except as otherwise specifically provided in this Section 10.2, where delivery or performance has been affected by fires, floods, embargoes, strikes, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, acts of God or acts or similar condition beyond such Party's reasonable control; provided that the Party affected by such a condition shall, within [**] days of its occurrence, give notice to the other Party stating the nature of the condition, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required and the nonperforming Party shall use commercially reasonable efforts to remedy its inability to perform. Notwithstanding the foregoing, in the event the suspension of performance continues for [**] days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the nonaffected Party may terminate this Agreement immediately by written notice to the affected Party.

10.3 Entire Agreement; Amendment.

(a) This Agreement, together with the Schedules and Exhibits attached hereto and the Quality Agreement, which shall be incorporated by reference hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements (including any terms and conditions previously agreed upon by the Parties), understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein.

(b) No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

10.4 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

10.5 Successors and Assigns. The terms and provisions hereof shall inure to the benefit of, and be binding upon, Intercept, PharmaZell and their respective successors and permitted assigns.

10.6 Governing Law. This Agreement shall be governed and interpreted in accordance with the laws of England and Wales, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; provided, however, for all intellectual property matters, this Agreement shall be governed and interpreted in accordance with the laws of New York, New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. To the extent not resolved pursuant to Section 10.7 or Section 10.8, venue for any litigation between the Parties shall be London, England or, with respect to intellectual property matters, New York, New York. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

10.7 Dispute Resolution.

(a) In the event of a dispute between the Parties, either Party may, by giving written notice of dispute to the other Party, request a meeting of authorized representatives of the Parties for the purpose of resolving the dispute. The Parties agree that, within [**] days after any such request, each Party shall designate a representative to participate in dispute resolution discussions that shall be held in [**] at a mutually acceptable time for the purpose of resolving the dispute. Each Party agrees to negotiate in good faith to resolve the dispute in a mutually acceptable manner.

(b) If for whatever reason the Parties are unable to resolve the dispute within [**] days after the issuance of a notice of dispute, then either Party may, by written notice to the other Party, submit the dispute to binding arbitration in accordance with the provisions of Section 10.8, except for those disputes excluded from Section 10.8 which shall be subject to the provisions of Section 10.6.

10.8 Arbitration.

(a) Except to the extent otherwise provided in Section 4.5, Section 7.5, or arising out of a dispute relating to Article 5, any dispute arising out of or relating to this Agreement, including the breach, termination or validity thereof, shall, after first being subject to negotiations between the Parties as provided in Section 10.7(a), be finally resolved by arbitration in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce ("**ICC Rules**") as then in effect, provided that, in the event and to the extent such rules conflict with the terms of this Section 10.8, the terms of this Section 10.8 shall govern. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The place of arbitration shall be [**]. The arbitration shall be conducted in the English language. The place of litigation for disputes relating to Article 5 shall be [**].

(b) Except as provided in Section 10.8(c), the arbitration shall be held before a single arbitrator, who shall be selected by agreement of the Parties, or, if the Parties cannot agree within [**] days after commencement of arbitration, then by the International Chamber of Commerce. The arbitrator selected pursuant to this Section 10.8(c) shall be a practicing or retired lawyer or retired judge and have experience relating to agreements concerning the marketing of pharmaceutical products in the United States.

(c) Notwithstanding Section 10.8(b), in the event that the dispute that is subject to arbitration is one in which a Party seeks to recover an amount of at least [**] from the other Party, then either Party shall have the option, exercisable by written notice to the other Party given at any time within [**] days after commencement of arbitration, to require that the arbitration be held before a panel of three (3) arbitrators. In such case, within [**] days after the provision of notice described in the preceding sentence, each Party shall select one person to act as arbitrator. If a Party shall fail within the designated time period to select an arbitrator, then the arbitrator to be selected by the Party shall be selected by the International Chamber of Commerce. The two (2) persons so selected as arbitrators shall select a third arbitrator within [**] days of their appointment. If the two (2) initially selected arbitrators are unable or fail to agree upon the third arbitrator, the third arbitrator shall be selected by the International Chamber of Commerce. Each arbitrator selected pursuant to this Section 10.8(c) shall be a practicing lawyer or retired judge and have experience relating to agreements concerning the marketing of pharmaceutical products in the United States.

(d) Each Party shall, upon the written request of the other Party, promptly provide the other Party with copies of documents relevant to the issues raised by the dispute on which the producing Party may rely in support of, or in opposition to, any claim or defense. Any dispute regarding discovery, or the relevance or scope thereof, shall be determined by the arbitrator(s), which determination shall be conclusive. To the extent reasonable under the circumstances and as agreed in writing by the Parties, all discoveries shall be completed within [**] days following the appointment of the arbitrator(s).

(e) It is the intent of the Parties that, barring extraordinary circumstances, and to the extent reasonable, arbitration proceedings will be concluded within [**] months from the date the arbitrator is appointed (or, where a panel of three (3) arbitrators is used, within [**] months from the date upon which the third arbitrator is appointed). The arbitrator(s) may extend this time limit in the interests of justice. Failure to adhere to this time limit shall not constitute a basis for challenging the award.

(f) Except as may be required by Applicable Law (including applicable securities laws or rules of a securities exchange) or as may be necessary to enforce the arbitration award or the provisions of this Section 10.8, and except for disclosures made by a Party to its accountants, insurers, consultants, or attorneys or to actual or potential lenders, non-public investors, rating agencies, acquirers, or business partners who are under obligations to the disclosing Party to hold the disclosed information in confidence, neither a Party nor its representatives may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of the other Party.

(g) The arbitrator(s) shall have discretion to allocate the Parties' costs and expenses for the arbitration (including attorneys' fees), the fees of the arbitrator(s), and the administrative fees of arbitration between the Parties in proportion to the extent to which they prevail. Failing such allocation, each Party shall bear its own costs and expenses and an equal share of the fees of the arbitrators and administrative fees of the arbitration.

10.9 Third Party Beneficiaries. Nothing in this Agreement shall be construed as giving any Person, other than the Parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.

10.10 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

10.11 Assignment. Except as expressly provided herein, neither Party may, without the prior written consent of the other Party, sell, transfer, assign, delegate, pledge, subcontract or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that (a) Intercept may, without such consent, assign this Agreement and its rights and obligations hereunder to an Affiliate, (b) Intercept may, without such consent, assign its rights and delegate its obligations under this Agreement in respect of Supplied Materials to the purchaser or sublicensee of Intercept's rights in and to such Supplied Materials or the relevant Product, (c) PharmaZell may, without such consent, assign this Agreement and its rights and obligations hereunder to one or more Affiliates, and (d) either Party may, without such consent, assign this Agreement and its rights and obligations hereunder to the purchaser of all or substantially all of its assets or to any successor entity or acquirer in the event of a merger, consolidation or change in control of such Party. Any attempt to assign, transfer, subcontract or delegate any portion of this Agreement in violation of this Section 10.11 shall be null and void. In the event either Party assigns all of its rights and delegates all of its obligations under this Agreement to another Person in accordance with the terms hereof and the assignee/delegee acquires all rights and assumes all obligations of its assignor/delegor under this Agreement, then the assignor/delegor shall cease to be a party to this Agreement or to have any rights or obligations under this Agreement from and after the effective date of such assignment or delegation. Except as provided in the preceding sentence, no assignment or delegation shall relieve the assignor or delegor of any of its obligations hereunder.

10.12 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by either Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion.

10.13 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein.

10.14 Independent Contractors. The status of the Parties under this Agreement shall be that of independent contractors. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer, employee, or joint venture relationship between the Parties. Neither Party shall have the right to enter into any agreements on behalf of the other Party, nor shall it represent to any Person that it has any such right or authority.

10.15 Construction. Unless the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words using the singular or plural number also include the plural or singular number, respectively; (c) the terms “hereof,” “herein,” “hereby” and derivative or similar words refer to this entire Agreement; (d) the terms “Article,” “Section,” “Schedule,” “Exhibit” or “clause” refer to the specified Article, Section, Schedule, Exhibit or clause of this Agreement; (e) the term “or” has, except where otherwise indicated, the inclusive meaning represented by the phrase “and/or”; (f) the term “including” or “includes” means “including without limitation” or “includes without limitation”; and (g) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto. Whenever this Agreement refers to a number of days, such number shall refer to calendar days unless Business Days are specified. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

10.16 Remedies. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable law or otherwise available except as expressly set forth herein.

10.17 Counterparts; Facsimile Execution. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument. Delivery of an executed counterpart of a signature page of this Agreement (and each amendment, modification and waiver in respect of it) by facsimile or other electronic transmission shall be as effective as delivery of a manually executed original counterpart of each such instrument.

10.18 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

10.19 Parent Guarantee. Intercept Parent hereby agrees to be jointly and severally liable for the prompt and complete performance of Intercept's financial obligations under this Agreement, and hereby guarantees the financial performance by Intercept of the obligations set forth in this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement to be effective as of the last date of signature below.

INTERCEPT PHARMA EUROPE LTD.

By: /s/ Steve Arnold

Name: Steve Arnold

Title: SVP

Date: August 12, 2016

PHARMAZELL GmbH

By: /s/ Oliver Bolzern

Name: Oliver Bolzern

Title: CEO

Date: August 12, 2016

AGREED TO AND ACCEPTED SOLELY FOR PURPOSES OF SECTION 10.19:

INTERCEPT PHARMACEUTICALS, INC.

By: /s/ Sandip Kapadia

Name: Sandip Kapadia

Title: CFO

Date: August 12, 2016

[Signature Page to Manufacturing and Supply Agreement]

SCHEDULE 1.40

Intercept Materials

[**]

Schedule 1.40 to Manufacturing and Supply Agreement

SCHEDULE 1.83

Form of Work Order

FOR ILLUSTRATION PURPOSES ONLY – DO NOT EXECUTE

WORK ORDER #____

This Work Order #____ ("Work Order") is entered into and effective with and as of the last signature to it by either Party by and between **Intercept Pharma Europe Ltd.** ("Intercept") and PharmaZell GmbH ("PharmaZell") and is subject to all of the terms and conditions of the Manufacturing and Supply Agreement between Intercept and PharmaZell, effective as of ____, 2016 (the "Agreement") and in accordance with this Work Order using, if applicable, the materials provided by Intercept hereunder.

Specifications supplied by Intercept: as in Quality Agreement signed September 12, 2014

Description of Services or Scope of Work: PharmaZell shall provide the following Supplied Material to Intercept: Work Order Description. *[Or insert Description, including any work product, reports, or presentations contemplated under this Agreement; please be as specific as possible]* or *[If applicable,* **"as outlined in Appendix 1 attached hereto and incorporated by reference.***"]*

Deliverables: Quantity of Supplied Materials.

Delivery Date: *[Insert desired Delivery Date]*

Place of Delivery: *[Insert desired Delivery location]*

Timelines and Milestones: PharmaZell will provide schedule and progress updates in accordance with the terms of the Agreement.

Compensation: Intercept shall pay the total sum not to exceed of **Total Estimated Work Amount** (the "Total Fee") in accordance with the commercial pricing set forth in the Agreement and in consideration for the performance of the above Supplied Material supplied. Payment shall be made in accordance with the details outlined in the Agreement.

OTHER TERMS TO BE ADDED AS AGREED

Capitalized terms contained in this Work Order and not otherwise defined herein, shall have the meaning ascribed to them in the Agreement.

This Work Order may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Work Order delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

[Remainder of Page Intentionally Blank]

IN WITNESS WHEREOF, each Party has executed this Work Order by a duly authorized individual effective as of the later of the signatures below.

INTERCEPT PHARMA EUROPE LTD.		**PHARMAZELL GMBH**	
By:	Form Only – Do Not Sign	By:	Form Only – Do Not Sign
Name:		Name:	
Title:		Title:	
Date:		Date:	

Schedule 1.83 to Manufacturing and Supply Agreement

SCHEDULE 2.1(d)

Approved Subcontractors and Activities

Subcontractor	Activity
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

SCHEDULE 2.2(a)

Existing Work Orders

[**]

Schedule 2.2(a) to Manufacturing and Supply Agreement

Schedule 2.2(b)

First New Work Order

[**]

Schedule 2.2(b) to Manufacturing and Supply Agreement

SCHEDULE 2.7(e)

Standard Yields

[**]

Schedule 2.7(e) to Manufacturing and Supply Agreement

Exhibit 31.1

CERTIFICATIONS

I, Mark Pruzanski, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Intercept Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

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

Exhibit 31.2

CERTIFICATIONS

I, Sandip Kapadia, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Intercept Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

By: /s/ Sandip Kapadia
Sandip Kapadia
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Intercept Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his or her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

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