

INTERCEPT PHARMACEUTICALS INC  
Form 10-Q  
November 06, 2017

**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, 2017**

**OR**

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

**For the transition period from                      to**

**Commission file number: 001-35668**

**INTERCEPT PHARMACEUTICALS, INC.**

**(Exact Name of Registrant as Specified in Its Charter)**

<b>Delaware</b> <b>(State or Other Jurisdiction of</b>	<b>22-3868459</b> <b>(I.R.S. Employer</b>
<b>Incorporation or Organization)</b>	<b>Identification Number)</b>
<b>10 Hudson Yards, 37<sup>th</sup> FL</b>	<b>10001</b>
<b>New York, NY</b> <b>(Address of Principal Executive Offices)</b>	<b>(Zip Code)</b>

**(646) 747-1000**

**(Registrant's Telephone Number, Including Area Code)**

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

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

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

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Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 September 30, 2017, there were 25,102,079 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,” “target,” “potential,” “warrant,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the potential benefit and commercial potential of Ocaliva<sup>®</sup> (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, Europe and other jurisdictions in which we have or may receive marketing authorization;
- the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;
- the timing of and our ability to obtain regulatory approval of OCA in indications other than PBC and regulatory approval of any other product candidates which we may develop;
- conditions that may be imposed by regulatory authorities on our marketing approvals for our products and 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 products or product candidates;
- our plans to research, develop and commercialize our products and product candidates;
- our ability to obtain and maintain intellectual property protection for our products and product candidates;
- our ability to successfully commercialize our products and product candidates;
- the size and growth of the markets for our products and product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any products, which may be affected by the reimbursement received from payors;
  - the success of competing drugs that are or become available;
  - regulatory developments in the United States and other countries;
  - the performance of our third-party suppliers and manufacturers;
- our collaborators’ election to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
  - our need for and ability to obtain additional financing;
- our estimates regarding expenses, revenues and capital requirements and the accuracy thereof;
  - our use of 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 March 1, 2017, 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 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. For the nine months ended September 30, 2016, adjusted operating expense also excludes a one-time \$45 million net expense for the settlement of a purported class action lawsuit. 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****(In thousands, except per share data)**

	September 30, 2017 (Unaudited)	December 31, 2016 (Audited)
Assets		
Current assets:		
Cash and cash equivalents	\$ 120,244	\$ 43,675
Investment securities, available-for-sale	372,506	645,710
Accounts receivable, net	14,487	9,126
Prepaid expenses and other current assets	14,278	9,354
Total current assets	521,515	707,865
Fixed assets, net	18,141	11,295
Inventory, net	3,897	2,279
Security deposits	16,873	17,814
Total assets	\$ 560,426	\$ 739,253
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	\$ 82,070	\$ 65,551
Short-term interest payable	3,737	7,267
Short-term portion of deferred revenue	1,782	5,694
Total current liabilities	87,589	78,512
Long-term liabilities:		
Long-term debt	351,984	341,356
Long-term other liabilities	6,068	-
Long-term portion of deferred revenue	3,118	4,453
Total liabilities	448,759	424,321
Stockholders' equity:		
Preferred stock par value \$0.001 per share; 5,000,000 shares authorized; none outstanding as of September 30, 2017 and December 31, 2016, respectively	-	-
Common stock par value \$0.001 per share; 45,000,000 shares authorized; 25,102,079 and 24,819,918 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	25	25
Additional paid-in capital	1,470,545	1,426,168
Accumulated other comprehensive loss, net	(632 )	(2,801 )

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Accumulated deficit	(1,358,271 )	(1,108,460 )
Total stockholders' equity	111,667	314,932
Total liabilities and stockholders' equity	\$ 560,426	\$ 739,253

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,	
	2017	2016	2017	2016
Revenue:				
Product revenue, net	\$40,889	\$4,732	\$91,933	\$4,807
Licensing revenue	445	445	1,336	6,336
Total revenue	41,334	5,177	93,269	11,143
Operating expenses:				
Cost of sales	172	-	548	-
Selling, general and administrative	61,356	52,802	189,363	197,382
Research and development	45,977	35,411	134,001	102,292
Total operating expenses	107,505	88,213	323,912	299,674
Operating loss	(66,171 )	(83,036 )	(230,643 )	(288,531 )
Other income (expense):				
Interest expense	(7,354 )	(7,065 )	(21,840 )	(7,065 )
Other income, net	924	1,286	3,388	2,807
Net loss	(6,430 )	(5,779 )	(18,452 )	(4,258 )
	\$ (72,601 )	\$ (88,815 )	\$ (249,095 )	\$ (292,789 )
Net loss per common and potential common share:				
Basic and diluted	\$(2.89 )	\$(3.59 )	\$(9.96 )	\$(11.90 )
Weighted average common and potential common shares outstanding:				
Basic and diluted	25,104	24,738	25,021	24,614

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,	
	2017	2016	2017	2016
Net loss	\$(72,601)	\$(88,815)	\$(249,095)	\$(292,789)
Other comprehensive loss:				
Unrealized gains (losses) on securities:				
Unrealized holding gains (losses) arising during the period	409	(1,073 )	1,114	966
Reclassification for recognized losses on marketable investment securities during the period	-	-	-	(52 )
Net unrealized gains (losses) on marketable investment securities	\$409	\$(1,073 )	\$1,114	\$914
Foreign currency translation adjustments	488	(691 )	1,055	(1,585 )
Comprehensive loss	\$(71,704)	\$(90,579)	\$(246,926)	\$(293,460)

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,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (249,095	) \$ (292,789 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	41,584	27,041
Amortization of investment premium	2,777	3,736
Amortization of deferred financing costs	1,052	326
Depreciation	3,256	2,187
Accretion of debt discount	9,576	3,001
Realized gain on investments	-	52
Changes in operating assets:		
Prepaid expenses and other current assets	(4,924	) (984 )
Accounts receivable	(5,361	) -
Inventory	(1,618	) -
Security deposits	-	(1,803 )
Changes in operating liabilities:		
Accounts payable, accrued expenses and other current liabilities	16,519	1,699
Long-term other liabilities	6,068	-
Interest payable	(3,530	) 3,738
Deferred revenue	(5,247	) 817
Net cash used in operating activities	(188,943	) (252,979 )
Cash flows from investing activities:		
Purchases of investment securities	(127,002	) (443,323 )
Refund of security deposits	941	-
Sales of investment securities	398,543	361,019
Purchases of equipment, leasehold improvements, and furniture and fixtures	(10,102	) (4,005 )
Net cash provided by (used in) investing activities	262,380	(86,309 )
Cash flows from financing activities:		
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, net	2,077	4,429
Net cash provided by financing activities	2,077	413,780
Effect of exchange rate changes	1,055	(2,018 )
Net increase in cash and cash equivalents	76,569	72,474
Cash and cash equivalents – beginning of period	43,675	32,742
Cash and cash equivalents – end of period	\$ 120,244	\$ 105,216

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.

**2. 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, 2017 are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2017. In the opinion of management, these unaudited condensed consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim unaudited condensed consolidated financial statements.

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, 2016, included in the Company’s 2016 Annual Report on Form 10-K filed with the SEC.

Certain reclassifications have been made to prior period amounts in the Company’s unaudited condensed consolidated statements of operations to conform to the current period presentation. The Company reclassified certain medical affairs costs of \$8.4 million and \$20.3 million from research and development expense to selling, general and administrative expense on the unaudited condensed consolidated statements of operations during the three and nine months ended September 30, 2016.

*Use of Estimates*

The preparation of these unaudited consolidated condensed 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.

### **3. Summary of Significant Accounting Policies**

The Company's significant accounting policies are described in Note 3 of Notes to Consolidated Financial Statements included in its Annual Report on Form 10-K for the year ended December 31, 2016.

#### ***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.

The Company commenced its commercial launch of Ocaliva<sup>®</sup> (obeticholic acid