

# INTERCEPT PHARMACEUTICALS INC

## FORM 10-Q (Quarterly Report)

Filed 05/10/17 for the Period Ending 03/31/17

|             |   |
|-------------|---|
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| CIK         | 0001270073  |
| Symbol      | ICPT  |
| SIC Code    | 2834 - Pharmaceutical Preparations                    |
| Industry    | Biotechnology & Medical Research                      |
| Sector      | Healthcare  |
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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 March 31, 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)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

10 Hudson Yards, 37<sup>th</sup> FL  
New York, NY  
(Address of Principal Executive Offices)

22-3868459  
(I.R.S. Employer  
Identification Number)

10001  
(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, 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.

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 April 28, 2017, there were 25,009,178 shares of common stock, \$0.001 par value per share, outstanding.

Intercept Pharmaceuticals, Inc.

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**FINANCIAL INFORMATION**

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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,” “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<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 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 we may develop such as INT-767;
- 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. 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 year ended December 31, 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)

|  | March 31,<br>2017<br>(Unaudited) | December 31,<br>2016<br>(Audited) |
|--|----------------------------------|-----------------------------------|
| <b>Assets</b>  |                                  |                                   |
| Current assets:  |                                  |                                   |
| Cash and cash equivalents  | \$ 66,950                        | \$ 43,675                         |
| Investment securities, available-for-sale  | 541,063                          | 645,710                           |
| Accounts receivable  | 10,625                           | 9,126                             |
| Prepaid expenses and other current assets  | 16,348                           | 9,354                             |
| Total current assets   | 634,986                          | 707,865                           |
| Fixed assets, net  | 14,518                           | 11,295                            |
| Inventory  | 2,116                            | 2,279                             |
| Security deposits  | 16,400                           | 17,814                            |
| Total assets   | <u>\$ 668,020</u>                | <u>\$ 739,253</u>                 |
| <b>Liabilities and Stockholders' Equity</b>  |                                  |                                   |
| Current liabilities:   |                                  |                                   |
| Accounts payable, accrued expenses and other liabilities   | \$ 62,923                        | \$ 65,551                         |
| Short-term interest payable  | 3,738                            | 7,267                             |
| Short-term portion of deferred revenue   | 6,019                            | 5,694                             |
| Total current liabilities  | 72,680                           | 78,512                            |
| Long-term liabilities:   |                                  |                                   |
| Long-term debt   | 344,825                          | 341,356                           |
| Long-term other liabilities  | 6,268                            | -                                 |
| Long-term portion of deferred revenue  | 4,009                            | 4,453                             |
| Total liabilities  | 427,782                          | 424,321                           |
| Stockholders' equity:  |                                  |                                   |
| Preferred stock par value \$0.001 per share; 5,000,000 shares authorized; none outstanding as of March 31, 2017 and December 31, 2016, respectively                                      | -                                | -                                 |
| Common stock par value \$0.001 per share; 45,000,000 shares authorized; 25,012,174 and 24,819,918 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively | 25                               | 25                                |
| Additional paid-in capital   | 1,441,501                        | 1,426,168                         |
| Accumulated other comprehensive loss, net  | (2,182)                          | (2,801)                           |
| Accumulated deficit  | (1,199,106)                      | (1,108,460)                       |
| Total stockholders' equity   | 240,238                          | 314,932                           |
| Total liabilities and stockholders' equity   | <u>\$ 668,020</u>                | <u>\$ 739,253</u>                 |

See accompanying notes to the condensed consolidated financial statements.

**INTERCEPT PHARMACEUTICALS, INC.**  
**Condensed Consolidated Statements of Operations**  
**(Unaudited)**  
**(In thousands, except per share amounts)**

|   | <b>Three Months Ended</b> |              |
|---|---------------------------|--------------|
|   | <b>March 31,</b>          |              |
|   | <b>2017</b>               | <b>2016</b>  |
| <b>Revenue:</b>   |                           |              |
| Product revenue, net  | \$ 20,603                 | \$ -         |
| Licensing revenue   | 445                       | 445          |
| Total revenue   | 21,048                    | 445          |
| <b>Operating expenses:</b>  |                           |              |
| Cost of sales   | 97                        | -            |
| Selling, general and administrative                                     | 61,082                    | 95,865       |
| Research and development  | 43,832                    | 31,980       |
| Total operating expenses  | 105,011                   | 127,845      |
| Operating loss  | (83,963)                  | (127,400)    |
| <b>Other income (expense):</b>  |                           |              |
| Interest expense  | (7,207)                   | -            |
| Other income, net   | 1,240                     | 726          |
|   | (5,967)                   | 726          |
| Net loss  | \$ (89,930)               | \$ (126,674) |
| <b>Net loss per common and potential common share:</b>                  |                           |              |
| Basic and diluted   | \$ (3.61)                 | \$ (5.17)    |
| <b>Weighted average common and potential common shares outstanding:</b> |                           |              |
| Basic and diluted   | 24,931                    | 24,495       |

See accompanying notes to the condensed consolidated financial statements .



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

|  | <b>Three Months Ended</b> |              |
|--|---------------------------|--------------|
|  | <b>March 31,</b>          |              |
|  | <b>2017</b>               | <b>2016</b>  |
| Net loss   | \$ (89,930)               | \$ (126,674) |
| Other comprehensive loss:  |                           |              |
| Unrealized gains (losses) on securities:   |                           |              |
| Unrealized holding gains arising during the period   | 414                       | 1,734        |
| Reclassification for recognized losses on marketable investment securities during the period | -                         | (80)         |
| Net unrealized gains on marketable investment securities                                     | \$ 414                    | \$ 1,654     |
| Foreign currency translation adjustments   | 205                       | (527)        |
| Comprehensive loss   | \$ (89,311)               | \$ (125,547) |

See accompanying notes to the condensed consolidated financial statements .

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

|  | <b>Three Months Ended March 31,</b> |              |
|--|-------------------------------------|--------------|
|  | <b>2017</b>                         | <b>2016</b>  |
| <b>Cash flows from operating activities:</b>                                       |                                     |              |
| Net loss   | \$ (89,930)                         | \$ (126,674) |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b> |                                     |              |
| Share-based compensation   | 14,061                              | 10,244       |
| Amortization of investment premium   | 1,022                               | 1,543        |
| Amortization of deferred financing costs   | 343                                 | -            |
| Depreciation   | 802                                 | 684          |
| Accretion of debt discount   | 3,126                               | -            |
| <b>Changes in operating assets:</b>  |                                     |              |
| Prepaid expenses and other current assets  | (6,994)                             | (7,088)      |
| Security deposits  | 1,414                               | -            |
| Accounts receivable  | (1,499)                             | -            |
| Inventory  | 163                                 | -            |
| <b>Changes in operating liabilities:</b>   |                                     |              |
| Accounts payable, accrued expenses and other current liabilities                   | (2,628)                             | (3,121)      |
| Litigation settlement  | -                                   | 55,000       |
| Long-term other liabilities  | 6,268                               | -            |
| Interest payable   | (3,529)                             | -            |
| Deferred revenue   | (119)                               | (445)        |
| Net cash used in operating activities  | (77,500)                            | (69,857)     |
| <b>Cash flows from investing activities:</b>                                       |                                     |              |
| Purchases of investment securities   | (21,246)                            | (35,318)     |
| Sales of investment securities   | 125,285                             | 123,006      |
| Purchases of equipment, leasehold improvements, and furniture and fixtures         | (4,025)                             | (2,407)      |
| Net cash provided by investing activities  | 100,014                             | 85,281       |
| <b>Cash flows from financing activities:</b>                                       |                                     |              |
| Proceeds from exercise of options, net   | 556                                 | 1,486        |
| Net cash provided by financing activities  | 556                                 | 1,486        |
| Effect of exchange rate changes  | 205                                 | (447)        |
| Net increase in cash and cash equivalents  | 23,275                              | 16,463       |
| Cash and cash equivalents – beginning of period                                    | 43,675                              | 32,742       |
| Cash and cash equivalents – end of period  | \$ 66,950                           | \$ 49,205    |

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 months ended March 31, 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 \$5.4 million from research and development expense to selling, general and administrative expense on the unaudited condensed consolidated statements of operations during the three months ended March 31, 2016.

*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.

**3. Summary of Significant Accounting Policies**

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

*Recent Accounting Pronouncements*

In May 2014, the Financial Accounting Standards Board (“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 evaluating which transition approach it will utilize and the impact of adopting ASU 2014-09, ASU 2016-08 and ASU 2016-10 on its condensed consolidated financial statements and related disclosures. The Company will adopt these standards with an effective date of January 1, 2018.

On August 27, 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"), which requires an entity to evaluate whether conditions or events, in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern for one year from the date the financial statements are issued or are available to be issued. The guidance became effective January 1, 2017. The Company adopted ASU No. 2014-15 on January 1, 2017, and its adoption did not have a material impact on the Company's financial statements.

In January 2016, FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact that ASU 2016-01 will have on its condensed consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02") 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 2016-02 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 ("ASU 2016-09") 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 adopted ASU 2016-09 during the first quarter of 2017. In connection with the adoption of this ASU, the Company elected to account for forfeitures as they occur and applied this change in accounting policy on a modified retrospective basis. As a result, the Company recorded a cumulative-effect adjustment to retained earnings which resulted in an increase to accumulated deficit of \$0.7 million with an offsetting increase to additional paid-in capital (zero net total equity impact) as of the date of adoption, related to additional stock compensation expense that would have been recognized on unvested outstanding options unadjusted for estimated forfeitures. As a result of this guidance, the Company also recorded \$58.7 million of additional deferred tax assets, which are fully offset by a valuation allowance. Other provisions of ASU 2016-09 had no impact on the Company's condensed consolidated financial statements.

#### **4. 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 March 31, 2017, the Company had achieved \$6.0 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 March 31, 2017 and 2016, the Company recorded licensing revenue of approximately \$0.4 million and \$0.4 million, respectively.

## 5. Cash, Cash Equivalents and Investments

The following table summarizes the Company's cash, cash equivalents and investments as of March 31, 2017 and December 31, 2016:

|  | As of March 31, 2017 |                        |                         |            |
|--|----------------------|------------------------|-------------------------|------------|
|  | Amortized Cost       | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|  | (In thousands)       |                        |                         |            |
| <b>Cash and cash equivalents:</b>            |                      |                        |                         |            |
| Cash and money market funds                  | \$ 66,950            | \$ -                   | \$ -                    | \$ 66,950  |
| <b>Investment securities:</b>                |                      |                        |                         |            |
| Commercial paper                             | 64,828               | -                      | (42)                    | 64,786     |
| Corporate debt securities                    | 453,145              | 12                     | (1,089)                 | 452,068    |
| U.S. government and agency securities        | 24,250               | -                      | (41)                    | 24,209     |
| Total investments                            | 542,223              | 12                     | (1,172)                 | 541,063    |
| Total cash, cash equivalents and investments | \$ 609,173           | \$ 12                  | \$ (1,172)              | \$ 608,013 |

  

|  | As of December 31, 2016 |                        |                         |            |
|--|-------------------------|------------------------|-------------------------|------------|
|  | Amortized Cost          | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|  | (In thousands)          |                        |                         |            |
| <b>Cash and cash equivalents:</b>            |                         |                        |                         |            |
| Cash and money market funds                  | \$ 43,675               | \$ -                   | \$ -                    | \$ 43,675  |
| <b>Investment securities:</b>                |                         |                        |                         |            |
| Commercial paper                             | 66,185                  | -                      | (71)                    | 66,114     |
| Corporate debt securities                    | 554,847                 | 14                     | (1,443)                 | 553,418    |
| U.S. government and agency securities        | 26,254                  | -                      | (76)                    | 26,178     |
| Total investments                            | 647,286                 | 14                     | (1,590)                 | 645,710    |
| Total cash, cash equivalents and investments | \$ 690,961              | \$ 14                  | \$ (1,590)              | \$ 689,385 |

As of March 31, 2017, the Company held a total of three positions that were in a continuous unrealized loss position for more than twelve months. The Company has determined that the unrealized losses are deemed to be temporary impairments as of March 31, 2017. The Company believes that the unrealized losses generally are caused by increases in the risk premiums required by market participants rather than an adverse change in cash flows or a fundamental weakness in the credit quality of the issuer or underlying assets. Because the Company has the ability and intent to hold these investments until a recovery of fair value, which may be maturity, it does not consider the investment in corporate debt securities to be other-than-temporarily impaired at March 31, 2017.

## 6. Fixed Assets, Net

Fixed assets are stated at cost and depreciated or amortized using the straight-line method based on useful lives as follows:

|                                | Useful lives<br>(Years) | March 31, 2017 |           | December 31, 2016 |  |
|--------------------------------|-------------------------|----------------|-----------|-------------------|--|
|                                |                         | (In thousands) |           |                   |  |
| Office equipment and software  | 3                       | \$ 4,700       | \$ 4,942  |                   |  |
| Leasehold improvements         | Over life of lease      | 10,240         | 6,668     |                   |  |
| Furniture and fixtures         | 7                       | 4,516          | 4,202     |                   |  |
| Subtotal                       |                         | 19,456         | 15,812    |                   |  |
| Less: accumulated depreciation |                         | (4,938)        | (4,517)   |                   |  |
| Fixed assets, net              |                         | \$ 14,518      | \$ 11,295 |                   |  |

## 7. Inventory

Inventories are stated at the lower of cost or market. Inventories consist of the following:

|                 | March 31, 2017  | December 31, 2016 |
|-----------------|-----------------|-------------------|
|                 | (In thousands)  |                   |
| Work-in-process | \$ 2,040        | \$ 2,207          |
| Finished goods  | 76              | 72                |
| Inventory, net  | <u>\$ 2,116</u> | <u>\$ 2,279</u>   |

## 8. Accounts Payable, Accrued Expenses and Other Liabilities

Accounts payable, accrued expenses and other liabilities consisted of the following:

|  | March 31, 2017   | December 31, 2016 |
|--|------------------|-------------------|
|  | (In thousands)   |                   |
| Accounts payable   | 7,279            | 6,722             |
| Accrued contracted services                              | \$ 37,208        | \$ 35,429         |
| Accrued employee compensation                            | 11,888           | 19,287            |
| Other liabilities  | 6,548            | 4,113             |
| Accounts payable, accrued expenses and other liabilities | <u>\$ 62,923</u> | <u>\$ 65,551</u>  |

## 9. Fair Value Measurements

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

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

- Unadjusted Quoted Prices — The fair value of an asset or liability is based on unadjusted quoted prices in active markets for identical assets or liabilities (Level 1).
- Pricing Models with Significant Observable Inputs — The fair value of an asset or liability is based on information derived from either an active market quoted price, which may require further adjustment based on the attributes of the financial asset or liability being measured, or an inactive market transaction (Level 2).
- Pricing Models with Significant Unobservable Inputs — The fair value of an asset or liability is primarily based on internally derived assumptions surrounding the timing and amount of expected cash flows for the financial instrument. Therefore, these assumptions are unobservable in either an active or inactive market (Level 3).

The Company considers an active market as one in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis. Conversely, the Company views an inactive market as one in which there are few transactions for the asset or liability, the prices are not current, or price quotations vary substantially either over time or among market makers. Where 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 and other observable inputs.

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

|                                       | Total             | Fair Value Measurements Using |                   |             |
|---------------------------------------|-------------------|-------------------------------|-------------------|-------------|
|                                       |                   | Level 1                       | Level 2           | Level 3     |
|                                       | (In thousands)    |                               |                   |             |
| <b>March 31, 2017</b>                 |                   |                               |                   |             |
| Assets:                               |                   |                               |                   |             |
| Money market funds                    | \$ 15,215         | \$ 15,215                     | \$ -              | \$ -        |
| Available for sale securities:        |                   |                               |                   |             |
| Commercial paper                      | 64,786            | -                             | 64,786            | -           |
| Corporate debt securities             | 452,068           | -                             | 452,068           | -           |
| U.S. government and agency securities | 24,209            | -                             | 24,209            | -           |
| Total financial assets:               | <u>\$ 556,278</u> | <u>\$ 15,215</u>              | <u>\$ 541,063</u> | <u>\$ -</u> |
| <b>December 31, 2016</b>              |                   |                               |                   |             |
| Assets:                               |                   |                               |                   |             |
| Money market funds                    | \$ 11,755         | \$ 11,755                     | \$ -              | \$ -        |

|                                       |                   |                  |                   |             |
|---------------------------------------|-------------------|------------------|-------------------|-------------|
| Available for sale securities:        |                   |                  |                   |             |
| Commercial paper                      | 66,114            | -                | 66,114            | -           |
| Corporate debt securities             | 553,418           | -                | 553,418           | -           |
| U.S. government and agency securities | 26,178            | -                | 26,178            | -           |
| Total financial assets                | <u>\$ 657,465</u> | <u>\$ 11,755</u> | <u>\$ 645,710</u> | <u>\$ -</u> |

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:

|   | <b>Fair Value as of</b> |                          |
|---|-------------------------|--------------------------|
|   | <b>March 31, 2017</b>   | <b>December 31, 2016</b> |
|   | (In thousands)          |                          |
| Due in one year or less                     | \$ 452,468              | \$ 456,184               |
| Due after 1 year through 5 years            | 88,595                  | 189,526                  |
| <b>Total investments in debt securities</b> | <b>\$ 541,063</b>       | <b>\$ 645,710</b>        |

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

## 10. Long-Term Debt

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

|                                   | <b>March 31, 2017</b> | <b>December 31, 2016</b> |
|-----------------------------------|-----------------------|--------------------------|
|                                   |                       | (In thousands)           |
| Long-term debt                    | \$ 344,825            | \$ 341,356               |
| Less current portion              | -                     | -                        |
| <b>Long-term debt outstanding</b> | <b>\$ 344,825</b>     | <b>\$ 341,356</b>        |

On July 6, 2016, the Company issued \$460.0 million aggregate principal amount of the 3.25% convertible senior notes due 2023 (“Convertible Notes”). The Company received net proceeds of \$447.6 million after deducting underwriting discounts and estimated offering expenses of approximately \$12.4 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 \$334.4 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 \$7.2 million and \$0 for the three months ended March 31, 2017 and 2016, respectively, related to the Convertible Notes. Accrued interest on the Convertible Notes was approximately \$3.7 million and \$7.3 million as of March 31, 2017 and December 31, 2016, respectively. The Company recorded debt issuance costs of \$12.4 million, which are being amortized using the effective interest method. As of March 31, 2017, \$11.4 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 March 31, 2017, the Company had outstanding borrowings of \$460.0 million related to the Convertible Notes.



## 11. Product Revenue, Net

The Company recognized net sales of Ocaliva of \$20.6 million and \$0 for the three months ended March 31, 2017 and 2016, respectively. The Company also recorded \$4.2 million and \$3.9 million in short-term portion of deferred revenue on its balance sheet, which represents product shipped to distributors, but not sold through as of March 31, 2017 and December 31, 2016, respectively.

The table below summarizes consolidated product revenue, net by region:

|                            | Three Months Ended March 31, |             |
|----------------------------|------------------------------|-------------|
|                            | 2017                         | 2016        |
|                            | (In thousands)               |             |
| Product revenue, net:      |                              |             |
| U.S.                       | \$ 19,777                    | \$ -        |
| ex-U.S.                    | 826                          | -           |
| Total product revenue, net | <u>\$ 20,603</u>             | <u>\$ -</u> |

## 12. Stock 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.

On January 1, 2017, the numbers of shares reserved for issuance under the 2012 Plan was increased by 993,558 shares, as a result of the automatic increase in shares reserved pursuant to the terms thereof.

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

The following table summarizes stock option activity during the three months ended March 31, 2017:

|                                  | Number<br>of Shares<br>(In thousands) | Weighted<br>Average<br>Exercise Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (years) | Aggregate<br>Intrinsic Value<br>(In thousands) |
|----------------------------------|---------------------------------------|---------------------------------------|---|--|
| Outstanding at December 31, 2016 | 1,553                                 | \$ 117.80                             | 7.4   | \$ 48,308                                      |
| Granted                          | 405                                   | \$ 112.88                             | -   | \$ -   |
| Exercised                        | (10)                                  | \$ 54.13                              | -   | \$ -   |
| Cancelled/forfeited              | (15)                                  | \$ 139.99                             | -   | \$ -   |
| Expired                          | (6)                                   | \$ 163.97                             | -   | \$ -   |
| Outstanding at March 31, 2017    | <u>1,927</u>                          | \$ 116.79                             | 7.7   | \$ 51,693                                      |
| Expected to vest                 | 1,927                                 | \$ 116.79                             | 7.7   | \$ 51,693                                      |
| Exercisable                      | 901                                   | \$ 94.24                              | 6.2   | \$ 47,078                                      |

As of March 31, 2017, there was approximately \$68.2 million of total unrecognized compensation expense related to the unvested stock options shown in the table above, which is expected to be recognized over a weighted average period of 2.9 years.

The fair value of the Company's option awards were estimated using the assumptions below:

|                          | <b>Three Months Ended March 31,</b> |              |
|--------------------------|-------------------------------------|--------------|
|                          | <b>2017</b>                         | <b>2016</b>  |
| Volatility               | 60.9 - 65.4%                        | 61.4 - 62.4% |
| Expected term (in years) | 6.0 - 9.9                           | 5.1 - 10.0   |
| Risk-free rate           | 2.0 - 2.4%                          | 1.1 - 1.8%   |
| Expected dividend yield  | —%                                  | —%           |

The following table summarizes the aggregate RSU and RSA activity during the three months ended March 31, 2017:

|  | <b>Number of</b> | <b>Weighted</b>     |               |
|--|------------------|---------------------|---------------|
|  | <b>Awards</b>    | <b>Average Fair</b> |               |
|  | (In thousands)   | <b>Value</b>        |               |
| Non-vested shares outstanding, December 31, 2016 | 381              | \$                  | 136.89        |
| Granted  | 210              | \$                  | 112.83        |
| Vested   | (70)             | \$                  | 123.80        |
| Forfeited  | (7)              | \$                  | 138.23        |
| Non-vested shares outstanding, March 31, 2017    | <u>514</u>       | \$                  | <u>128.84</u> |

As of March 31, 2017, there was approximately \$59.0 million of total unrecognized compensation expense related to unvested RSUs and RSAs, which is expected to be recognized over a weighted average period of 2.8 years.

The Company accounts for forfeitures when they occur. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest. When performance based grants are issued, the Company recognizes no expense until achievement of the performance requirement is deemed probable.

Stock-based compensation expense has been reported in our statements of operations as follows:

|                                     | <b>Three Months Ended March 31,</b> |                  |
|-------------------------------------|-------------------------------------|------------------|
|                                     | <b>2017</b>                         | <b>2016</b>      |
|                                     | (In thousands)                      |                  |
| Selling, general and administrative | \$ 8,974                            | \$ 5,750         |
| Research and development            | 5,087                               | 4,494            |
| Total stock-based compensation      | <u>\$ 14,061</u>                    | <u>\$ 10,244</u> |

### 13. Net Loss Per Share

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

|  | <b>Three Months Ended March 31,</b> |              |
|--|-------------------------------------|--------------|
|  | <b>2017</b>                         | <b>2016</b>  |
| (In thousands, except per share amounts)   |                                     |              |
| <b>Historical net loss per share</b>   |                                     |              |
| Numerator:   |                                     |              |
| Net loss attributable to common stockholders                                       | \$ (89,930)                         | \$ (126,674) |
| Denominator:   |                                     |              |
| Weighted average shares used in calculating net loss per share - basic and diluted | 24,931                              | 24,495       |
| Net loss per share:  |                                     |              |
| Basic and diluted  | \$ (3.61)                           | \$ (5.17)    |

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

|                        | <b>Three Months Ended March 31,</b> |             |
|------------------------|-------------------------------------|-------------|
|                        | <b>2017</b>                         | <b>2016</b> |
| (In thousands)         |                                     |             |
| Convertible Notes      | 2,316                               | -           |
| Options                | 1,927                               | 1,663       |
| Restricted stock units | 514                                 | 352         |
| Total                  | 4,757                               | 2,015       |

## 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, 2016 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2017. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Item 1.A. "Risk Factors" of our Annual Report on Form 10-K and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements.*

### Overview

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat 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 candidate, 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 in the United States shortly after receiving such marketing approval, and Ocaliva is now available to patients primarily through a network of specialty pharmacy distributors. In December 2016, the European Commission granted conditional approval for Ocaliva for the treatment of PBC and we commenced our European commercial launch in January 2017. 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. 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. In May 2017, we completed enrollment of the interim analysis cohort for the REGENERATE trial. We anticipate top-line results from the interim analysis in the first half of 2019. 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 mid-2017. We continue to work towards expanding our overall NASH development program with additional trials and studies, including a Phase 3 trial in NASH patients with cirrhosis, which we expect to initiate in the second half of 2017.

In addition to PBC and NASH, we continue to invest in research of OCA for additional patient populations with other liver diseases. In September 2016, we completed enrollment of the targeted number of patients in our Phase 2 AESOP trial in PSC to evaluate the effects of 24 weeks of treatment with varying doses of OCA compared to placebo. We expect top-line results from the AESOP trial in mid-2017. In October 2015, we initiated a Phase 2 clinical trial, known as the CARE trial, of OCA in pediatric patients with biliary atresia. This trial will evaluate the effects of 11 weeks of OCA treatment where patients with biliary atresia will be randomized to varying doses of OCA or a control group receiving only their current treatment. We have completed a Phase 1 clinical trial of our second product candidate to enter clinical development, called INT-767, a dual FXR and TGR5 agonist, in healthy volunteers. We plan to initiate a Phase 2 trial of INT-767 in NASH patients with liver fibrosis in the second half of 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 March 31, 2017 and 2016 was approximately \$89.9 million and \$126.7 million, respectively. As of March 31, 2017, we had an accumulated deficit of approximately \$1.2 billion. 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 operating losses for at least the next several years as we:

- continue to commercialize Ocaliva for PBC in the United States and Europe;
- 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; and
- add infrastructure and personnel in the United States and internationally to support our product development and commercialization efforts and operations 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 we are able to consistently generate profits from our operations and become profitable, 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.

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

## **Recent Developments**

### *Completion of Enrollment of Phase 3 REGENERATE Trial Interim Analysis Cohort*

On May 4, 2017, we announced the completion of enrollment of the interim analysis cohort for the Phase 3 REGENERATE trial. We anticipate top-line results from the interim analysis in the first half of 2019.

### *Appointment of David Ford as Chief Human Resources Officer*

On May 4, 2017, we announced the appointment of David Ford as Chief Human Resources Officer effective May 8, 2017.

Mr. Ford, age 49, brings over 25 years of experience in a variety of human resources roles across the United States, Europe, Latin America and New Zealand. Prior to joining us, Mr. Ford spent nearly 15 years at Sanofi, where most recently he served as Vice President Human Resources for the Sanofi Genzyme global business unit starting in 2016. Prior to that role, from 2011 until 2016, Mr. Ford served as Vice President Human Resources for the Sanofi North American businesses. Mr. Ford joined the pharmaceutical industry in 2002 as the HR Director – United Kingdom and Republic of Ireland for Sanofi-Synthelabo. Mr. Ford holds a master's degree in business administration from INSEAD, Fontainebleau (France).

## **Financial Overview**

### **Revenue**

We commenced our commercial launch of Ocaliva for use in PBC in the United States in June 2016. In December 2016, the European Commission granted conditional approval for Ocaliva for the treatment of PBC and we commenced our European commercial launch in January 2017.

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.

### *Product Revenue, Net*

We provide the right of return to our customers for unopened product for a limited time before and after its expiration date. Given our limited sales history for Ocaliva and the inherent uncertainties in estimating product returns, we have determined that the shipments of Ocaliva made to our customers thus far do not meet the criteria for revenue recognition at the time of shipment. Accordingly, we recognize revenue when the product is sold through by our customers, provided all other revenue recognition criteria are met. We invoice our customers upon shipment of Ocaliva to them and record accounts receivable, with a corresponding liability for deferred revenue equal to the gross invoice price. We then recognize revenue when Ocaliva is sold through as product is dispensed directly to the patients.

We recognized net sales of Ocaliva of \$20.6 million and \$0 for the three months ended March 31, 2017 and 2016, respectively. We also recorded \$4.2 million and \$3.9 million in the short-term portion of deferred revenue on our balance sheet, which represents product shipped to distributors, but not sold through as of March 31, 2017 and December 31, 2016, respectively.

We have written contracts with each of our customers and delivery occurs when the customer receives Ocaliva. We evaluate the creditworthiness of each of our customers to determine whether collection is reasonably assured. In order to conclude that the price is fixed and determinable, we must be able to (i) calculate our gross product revenues from the sales to our customers and (ii) reasonably estimate our net product revenues. We calculate gross product revenues based on the wholesale acquisition cost that we charges our customers for Ocaliva. We estimate net product revenues by deducting from our 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.

### *Licensing Revenue*

We recognize revenue derived from our collaborative agreements for the development and commercialization of certain of our product candidates. In March 2011, we 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 March 31, 2017, we have achieved \$6.0 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 \$0.4 million in license revenue resulting from the amortization of the up-front payments under the collaboration agreement for the three months ended March 31, 2017 and 2016. 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.

### *Selling, General and Administrative Expenses*

Our selling, general and administrative expenses, excluding the one-time net expense of \$45.0 million attributable to the settlement of a purported securities class action lawsuit in 2016, have increased and we expect to continue to incur significant expenses due to the commercialization of Ocaliva for PBC in the United States and Europe, the potential commercialization of OCA in PBC in other international markets 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 abroad, which will increase our selling, general and administration expenses. We believe that these activities will result in costs related to the hiring of additional personnel, fees for outside consultants, lawyers and accountants, and the maintenance of facilities. We have also incurred and expect to 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 undertaking worldwide product launches.

### *Research and Development Expenses*

Since our inception, we have focused significant resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. We recognize research and development expenses as they are incurred.

Our research and development expenses have increased and we expect to continue to incur significant expenses due to our preclinical studies and clinical trials and other research and development efforts. 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.

## Results of Operations

### Comparison of the Three Months Ended March 31, 2017 and 2016

The following table summarizes our results of operations for each of the three months ended March 31, 2017 and 2016, together with the changes in those items in dollars:

|                                     | Three Months Ended March 31, |              | Dollar Change |
|-------------------------------------|------------------------------|--------------|---------------|
|                                     | 2017                         | 2016         |               |
|                                     | (In thousands)               |              |               |
| Revenue:                            |                              |              |               |
| Product revenue, net                | \$ 20,603                    | \$ -         | \$ 20,603     |
| Licensing revenue                   | 445                          | 445          | -             |
| Total revenue                       | 21,048                       | 445          | 20,603        |
| Operating expenses:                 |                              |              |               |
| Cost of sales                       | 97                           | -            | 97            |
| Selling, general and administrative | 61,082                       | 95,865       | (34,783)      |
| Research and development            | 43,832                       | 31,980       | 11,852        |
| Total operating expenses            | 105,011                      | 127,845      | (22,834)      |
| Operating loss                      | (83,963)                     | (127,400)    | 43,437        |
| Other income (expense):             |                              |              |               |
| Interest expense                    | (7,207)                      | -            | (7,207)       |
| Other income, net                   | 1,240                        | 726          | 514           |
|                                     | (5,967)                      | 726          | (6,693)       |
| Net loss                            | \$ (89,930)                  | \$ (126,674) | \$ 36,744     |

#### Revenues

Product revenue, net was approximately \$20.6 million and \$0 for the three months ended March 31, 2017 and 2016, respectively. We commenced our commercial launch in the United States for Ocaliva in PBC in June 2016 and in certain European countries in 2017. We recognized product revenue, net of \$19.8 million and \$0.8 million in the U.S. and ex-U.S. countries, respectively, in the three months ended March 31, 2017. For each of the three months ended March 31, 2017 and 2016, licensing revenue was approximately \$0.4 million which resulted from the recognition of development and regulatory milestones and amortization of the up-front payments under the collaboration agreement with Sumitomo Dainippon.

#### Cost of sales

Cost of sales was \$0.1 million and \$0 for the three months ended March 31, 2017 and 2016, respectively, due to the commercial launch in the United States for Ocaliva in PBC in June 2016 and in certain European countries in 2017.

#### Selling, general and administrative expenses

Selling, general and administrative expenses were \$61.1 million and \$95.9 million for the three months ended March 31, 2017 and 2016, respectively. The \$34.8 million net decrease between periods is primarily due to the one-time net expense of \$45.0 million attributable to the settlement of a purported securities class action lawsuit in 2016, along with decreases in indirect expenses (rent, travel, and product-related legal costs) of \$3.0 million and consultant spend of \$4.8 million. These decreases were partially offset by increased expenses of approximately \$12.1 million in Ocaliva commercialization activities and market research and additional personnel-related costs of approximately \$6.1 million to support our commercial and international initiatives.

#### Research and development expenses

Research and development expenses were \$43.8 million and \$32.0 million for the three months ended March 31, 2017 and 2016, respectively, representing a net increase of \$11.8 million. This net increase in research and development expense primarily reflects increases in OCA research and development activities of approximately \$11.6 million to support our development activities and an increase of \$0.9 million of compensation-related costs, partially offset by a decrease in INT-767 research and development activities of \$0.7 million.

### *Interest expense*

Interest expense was \$7.2 million and \$0 for the three months ended March 31, 2017 and 2016, respectively due to the issuance of our 3.25% convertible senior notes due 2023 or Convertible Notes, in July 2016.

### *Other income, net*

Other income, net was \$1.2 million and \$0.7 million in the three months ended March 31, 2017 and 2016, respectively. The \$0.5 million increase is primarily attributable to interest income earned on cash, cash equivalents and investment securities, which increased compared to the prior year period primarily due to the net proceeds from the issuance of our Convertible Notes in July 2016.

### *Income taxes*

For the three months ended March 31, 2017 and 2016, 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 March 31, 2017, we had an accumulated deficit of \$1.2 billion. 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 be significant 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 \$46.1 million). As of March 31, 2017, we had cash, cash equivalents and investment securities of \$608.0 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in cash and money market bank accounts and investments, all of which have maturities of less than two years.

### ***Cash Flows***

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

|                                 | <b>Three Months Ended March 31,</b> |             |
|---------------------------------|-------------------------------------|-------------|
|                                 | <b>2017</b>                         | <b>2016</b> |
|                                 | (In thousands)                      |             |
| Net cash provided by (used in): |                                     |             |
| Operating activities            | \$ (77,500)                         | \$ (69,857) |
| Investing activities            | 100,014                             | 85,281      |
| Financing activities            | 556                                 | 1,486       |

*Operating Activities.* Net cash used in operating activities of approximately \$77.5 million during the three months ended March 31, 2017 was primarily a result of our \$89.9 million net loss and a net decrease in operating assets and liabilities of \$6.9 million, partially offset by \$14.1 million in share-based compensation, \$3.1 million for accretion of the discount on our Convertible Notes, \$1.0 million for the amortization of investment premium and \$0.8 million of depreciation.

Net cash used in operating activities of \$69.9 million during the three months ended March 31, 2016 was primarily a result of our \$126.7 million net loss, partially offset by \$10.2 million for share-based compensation, the amortization of investment premium of \$1.5 million and net changes in operating assets and liabilities of \$10.2 million, including the \$45.0 million net expense for the settlement of the purported class action lawsuit.

*Investing Activities.* For the three months ended March 31, 2017, net cash provided by investing activities primarily reflects the sale of investment securities of \$125.3 million, partially offset by the purchase of investment securities of \$21.2 million and \$4.0 million of capital expenditures related to the build out of our new corporate office.

For the three months ended March 31, 2016, net cash provided by investing activities primarily reflects the sale of investment securities of \$123.0 million, partially offset by the purchase of investment securities of \$35.3 million and \$2.4 million of capital expenditures related to our offices.



*Financing Activities* . Net cash provided by financing activities in the three months ended March 31, 2017 consisted primarily of \$0.6 million from the exercise of options to purchase common stock.

Net cash provided by financing activities in the three months ended March 31, 2016 consisted primarily of \$1.5 million from the exercise of options to purchase common stock.

### **Future Funding Requirements**

While we commenced our commercial launch of Ocaliva for use in PBC in the United States and Europe, we cannot predict the period, if any, in which material net cash inflows from sales of OCA or our other product candidates can sustain our operations. We expect to continue to incur significant expenses 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 expenses in connection with increases in our product development, scientific, commercial and administrative personnel and expansion of our infrastructure in the United States and abroad. We anticipate that we will need substantial additional funding in connection with our continuing operations.

As of March 31, 2017, we had \$608.0 million in cash, cash equivalents and investment securities. We currently project adjusted operating expenses in the range of \$380 million to \$420 million in the fiscal year ending December 31, 2017, which excludes stock-based compensation and other non-cash items. These expenses are planned to support the continued commercialization of Ocaliva in PBC in the United States and other markets, the continued clinical development for OCA in PBC and NASH and PSC and the continued development of INT-767 and our other earlier stage pipeline programs. We may make additional investments over 2017 as our business evolves. Our adjusted operating expense estimate for 2017 is higher than our adjusted operating expenses for 2016 reflecting continued investment in clinical development programs and commercialization activities.

Adjusted operating expense is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP. For the year ended December 31, 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. 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 and the European Union;
- prepare for and initiate the commercial launch of Ocaliva in PBC in certain other target markets across the world, but not commercially launch Ocaliva in PBC in non-target countries across the world;
- continue and expand our clinical development programs for OCA in PBC and NASH, such as continuing, but not completing, our planned Phase 3 clinical program for OCA in NASH, including the REGENERATE trial, and our ongoing COBALT confirmatory clinical outcomes trial of OCA in PBC; and
- advance the continued development of INT-767, for which we completed a Phase 1 clinical trial in 2016, 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 funding 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 and the European Union;
- our ability to receive marketing approval of Ocaliva for PBC in countries outside of the United States and the European Union based on our regulatory submissions package and our work completed to date, including the willingness of the relevant regulatory authorities to accept the POISE trial, which is our completed Phase 3 clinical trial for PBC;

- the degree of effort and time needed to prepare for and initiate the commercial launches of Ocaliva in PBC outside of the United States and the European Union 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 any modifications we may be required to make to the COBALT trial as part of our post-marketing requirements to the FDA or the EMA;
- 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 and our product candidates in preclinical development such as INT-777;
- the 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 products and product candidates;
- market acceptance of our products and product candidates, which may be affected by reimbursement 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 consistently generate profits from our operations and become profitable, 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**

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 for the year ended December 31, 2016.

#### **Off-Balance Sheet Arrangements**

As of March 31, 2017, 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 for the year ended December 31, 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 March 31, 2017, 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 March 31, 2017 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. We do not, however, expect such pending legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

### **Item 1A. Risk Factors.**

There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the period ended December 31, 2016 and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission. For a further discussion of our Risk Factors, refer to the “Risk Factors” discussion contained in such filings.

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

#### **Recent Sales of Unregistered Securities**

Set forth below is information regarding securities sold by us during the three months ended March 31, 2017 that were not registered under the Securities Act of 1933, as amended, or Securities Act. Also included is the consideration, if any, received by us for the securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

Between January 1 and March 31, 2017, 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: May 10, 2017

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

Date: May 10, 2017

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

## Exhibit Index

| Exhibit Number | Description of Exhibit   |
|----------------|--|
| 10.1           | Employment Agreement by and between the Registrant and Jerome B. Durso, effective as of February 15, 2017.+  |
| 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 March 31, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at March 31, 2017 (unaudited) and December 31, 2016 (audited), (ii) Condensed Consolidated Statements of Operations for the three month periods ended March 31, 2017 and 2016 (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Loss for the three month periods ended March 31, 2017 and 2016, (iv) Condensed Consolidated Statements of Cash Flows for the three month periods ended March 31, 2017 and 2016 (unaudited) and (v) Notes to Condensed Consolidated Financial Statements (unaudited). |

+ Management contract or compensatory plan or arrangement.

**EMPLOYMENT AGREEMENT**

THIS EMPLOYMENT AGREEMENT (the "Agreement"), made effective as of February 15, 2017, is entered into by Intercept Pharmaceuticals, Inc. (the "Company") and Jerome Durso ("Executive").

WHEREAS, the Company desires to employ Executive, and Executive desires to be employed by the Company.

NOW THEREFORE, in consideration of the mutual covenants and promises contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties to this Agreement, the parties agree as follows:

1. Term of Employment. The Company hereby agrees to employ Executive, and Executive hereby accepts employment with the Company, upon the terms set forth in this Agreement, for the period commencing on February 23, 2017 or such date as may be otherwise agreed upon with the Company (the "Commencement Date") and ending on the one year anniversary thereof, unless sooner terminated in accordance with the provisions of Section 4 (such period, the "Initial Term"); provided, however, that on each anniversary of the Commencement Date, the term of employment under this Agreement shall be automatically extended for an additional one-year period (each such period, a "Subsequent Period") unless terminated sooner pursuant to Section 4 or if, at least thirty (30) days prior to the applicable anniversary date, either Executive or the Company provides written notice to the other party electing not to extend. The Initial Term together with each Subsequent Term, if any, are referred to hereinafter as the "Agreement Term."

2. Title; Capacity. During the Agreement Term, the Company will employ Executive as its Chief Operating Officer to perform the duties and responsibilities inherent in such position and such other duties and responsibilities consistent with such position as the Chief Executive Officer of the Company (the "CEO") shall from time to time reasonably assign to him. On an annual basis, the Company's Board of Directors (the "Board") in consultation with Executive and the CEO, will set mutually agreeable and reasonably attainable, specific goals pursuant to the objectives of the Company as in effect from time to time. Executive shall report directly to the CEO and shall be subject to the supervision of, and shall have such authority as is delegated to Executive by, the CEO, which authority shall be sufficient to perform Executive's duties hereunder. Executive will be based at the Company's headquarters in New York, New York. Subject to Section 4.3 below, the location of Executive's employment is subject to change during the course of the Agreement Term as determined by the CEO in consultation with the Executive. Executive hereby accepts such employment and agrees to undertake the duties and responsibilities inherent in such position and such other duties as may be reasonably assigned to Executive. Executive shall devote substantially all of his business time, energies and attention in the performance of the foregoing services. Notwithstanding the foregoing, nothing herein shall preclude Executive from (i) performing services for such other companies as the Company may designate or permit, (ii) serving, with the prior written consent of the Board, which consent shall not be unreasonably withheld, as an officer or member of the boards of directors or advisory boards (or their equivalents in the case of a non-corporate entity) of non-competing businesses, (iii) serving as an officer or a member of charitable, educational or civic organizations, (iv) engaging in charitable activities and community affairs, and (v) managing Executive's personal investments and affairs; provided, however, that the activities set out in clauses (i) – (v) shall be limited by Executive so as not to materially interfere, individually or in the aggregate, with the performance of Executive's duties and responsibilities hereunder.

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3. Compensation and Benefits.

3.1 Salary. The Company shall pay Executive an initial annualized base salary of \$520,000.00, payable in accordance with the Company's regular payroll practices. Such base salary shall be subject to annual review and increase (but not decrease) as may be determined and approved by the Board or the Company's Compensation Committee in its sole discretion.

3.2 Bonuses.

(a) Annual Bonus. At the end of a given fiscal year, Executive will be eligible to receive a bonus equal to up to 50% of his base salary in effect at the end of such fiscal year. Executive's annual bonus for the fiscal year in which the Commencement Date occurs shall be based upon his annualized base salary and shall not be prorated. The amount of any such bonus shall be based on factors including, but not limited to, Executive's achievement, as determined by the Board or the Compensation Committee in its sole discretion, of mutually agreeable reasonable goals and milestones established in advance by the Board or the Compensation Committee in consultation with the CEO and Executive. The period for calculation of the bonus shall be consistent with the Company's fiscal year. Such bonus, if any, will be paid to Executive on or after January 1 and in any case no later than March 15 of the immediately succeeding fiscal year. The bonus shall be paid in cash; provided that, if requested by Executive and approved by the Board, some or all of the bonus may be paid in equity under the Company's stockholder approved stock plan then in effect (valued at the fair market value thereof), or any combination of the foregoing. To the extent that the Company is required pursuant to Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act to develop and implement a policy (the "Policy") providing for the recovery from the Executive of any payment of incentive-based compensation paid to the Executive that was based upon erroneous data contained in an accounting statement, this Agreement shall be deemed amended and the Policy incorporated herein by reference as of the date that the Company takes all necessary corporate action to adopt the Policy, without requiring any further action of the Company or the Executive, provided that any such Policy shall only be binding on the Executive if the same Policy applies to the Company's other executive officers.

3.3 Equity Awards.

(a) On the Commencement Date, the Company shall grant Employee (i) a stock option under its 2012 Equity Incentive Plan (the "2012 Plan") to purchase 20,000 shares of the Company's common stock at a per share exercise price equal to the closing price of the common stock on the date of grant (the "Time-Based Option"), and (ii) a restricted stock award for 15,000 shares of the Company's common stock (the "Restricted Stock").

(b) Each of the Time-Based Option and the Restricted Stock will be evidenced in writing by an agreement provided by the Company. The Time-Based Option shall vest as follows: (i) one-quarter of the Time-Based Option will vest on the first anniversary of the Commencement Date; and (ii) the remaining balance will vest in equal monthly installments in arrears over the three (3) year period commencing on the first anniversary of the Commencement Date and ending on the fourth anniversary of the Commencement Date, all subject to Employee's continued employment by the Company and the 2012 Plan, except as otherwise set forth herein. The Time-Based Option agreement will specify that vested options shall be exercisable for up to ten (10) years, subject to the terms of this Agreement and the 2012 Plan. The shares underlying the Restricted Stock shall vest as follows: (x) one-quarter of the shares underlying the Restricted Stock will vest on the first anniversary of the Commencement Date; and (y) the remaining balance will vest in equal quarterly installments in arrears over the three (3) year period commencing on the first anniversary of the Commencement Date and ending on the fourth anniversary of the Commencement Date, all subject to Employee's continued employment by the Company and the 2012 Plan, except as otherwise set forth herein.

(c) At the sole discretion of the Board or the Company's Compensation Committee, additional stock options or other equity-based awards may be granted to Executive from time to time.

3.4 Fringe Benefits. Executive shall be entitled to participate in all bonus and benefit programs that the Company establishes and makes available to its U.S.-based executives and/or employees from time to time, including, but not limited to, health care plans, dental care plans, vision care plans, supplemental retirement plans, life insurance plans, disability insurance plans and incentive compensation plans, to the extent that Executive is eligible under, and subject to the terms and conditions of, the applicable plan documents governing such programs. The Company shall pay 100% of the premium cost for health insurance coverage for Executive, his spouse and children, provided that his spouse and dependents are not covered by an equivalent health insurance plan provided by his spouse's employer. Executive shall be eligible to accrue up to four (4) weeks of paid vacation each calendar year (to be taken at such times and in such number of days as Executive shall determine in consultation with the CEO and in a manner so as not to impair or otherwise interfere with Executive's ability to perform his duties and responsibilities hereunder). The vacation days for which Executive is eligible shall accrue at the rate of 1.67 days per month that Executive is employed during such calendar year. Vacation accrual will be capped in accordance with the Company's policies. When Executive's accrued vacation reaches the cap, he will not accrue additional vacation time until some of the previously accrued vacation is used and the accrued amount falls below the cap. Executive shall also be eligible for paid holidays and paid sick days annually, in accordance with the Company's policies for its senior executives as in effect from time to time. At the end of each calendar year, all unused sick days and personal days shall be forfeited

3.5 Reimbursement of Expenses. The Company shall reimburse Executive for reasonable travel, entertainment and other expenses incurred or paid in connection with, or related to the performance of Executive's duties, responsibilities or services under this Agreement, upon presentation by Executive of documentation, expense statements, vouchers and/or such other supporting information as the Company may request. Executive must submit proper documentation for each such expense within sixty (60) days after the later of (i) his incurrence of such expense or (ii) his receipt of the invoice for such expense. The Company will reimburse Executive for that expense within thirty (30) days after receipt of the documentation.



3.6 Counsel Fees. The Company shall seek the approval of the Compensation Committee of the Board at the next scheduled meeting to provide Executive on a pre-tax, gross basis an amount equal to \$5,000 to be used, at his discretion, for the payment of any attorney's fees incurred in reviewing and negotiating this Agreement.

3.7 Withholdings. Payments made under this Section 3 shall be subject to applicable federal, state and local taxes and withholdings, if any.

4. Termination of Employment Period. The Agreement Term shall terminate upon the occurrence of any of the following:

4.1 Expiration of the Agreement Term. This Agreement shall expire at the end of the Agreement Term; provided, that notice is given in accordance with Section 1 of this Agreement.

4.2 Termination by the Company for Cause. At the election of the Company, the Executive may be terminated by the Company for Cause (as defined below), immediately following written notice by the Company to Executive, which notice shall identify in reasonable detail the Cause upon which termination is based, except that for reason 4.2(a)(iv) below, termination may not occur prior to the expiration of the thirty (30) day period to cure. For the purposes of this Agreement, "Cause" for termination shall be deemed to exist upon:

(a) a good faith finding by the Company that (i) Executive has engaged in material dishonesty, willful misconduct or gross negligence in connection with the performance of his duties; (ii) Executive has committed any act of fraud or embezzlement with respect to the Company or any of its Affiliates; (iii) Executive has breached or has threatened to breach his/her Invention, Non-Disclosure, and Non-Solicitation Agreement; or (iv) Executive has materially breached this Agreement or any other written agreement between Executive and the Company, and Executive has failed to cure such conduct or breach within thirty (30) days after his receipt of written notice from the Company of such breach; or

(b) Executive's conviction, guilty plea, or entry of nolo contendere to any crime involving moral turpitude, fraud or embezzlement, or any felony.

4.3 Termination By Executive with Good Reason. Executive may terminate the Agreement Term with Good Reason. For purposes of this Agreement, "Good Reason" means the occurrence, without Executive's written consent, of any of the events or circumstances set forth in clauses (a) through (c) below. In addition, notwithstanding the occurrence of any of the events enumerated in clauses (a) through (c), such occurrence shall not be deemed to constitute Good Reason if, within thirty (30) days after the Company's receipt of written notice from Executive of the occurrence or existence of an event or circumstance enumerated in clauses (a) through (c), such event or circumstance has been remedied by the Company. Executive shall not be deemed to have terminated his employment with Good Reason unless Executive first delivers a written notice of termination to the Company identifying in reasonable detail the acts or omissions constituting Good Reason within ninety (90) days after their occurrence and the provision of this Agreement relied upon, such acts or omissions are not cured by the Company within thirty (30) days of the receipt of such notice, and Executive actually ends his employment within one-hundred and twenty (120) days after the Company's failure to cure.

(a) the assignment to Executive of duties inconsistent in any material respect with Executive's position as Chief Operating Officer (including status, offices, titles, authority, or responsibilities) or any other action or omission by the Company which results in a material diminution in Executive's position, status, offices, titles, authority, responsibilities, or reporting requirements;

(b) a change by the Company in the location at which Executive performs his principal duties for the Company to a different location that is outside a radius of fifty (50) miles from (i) Executive's principal residence immediately prior to the date on which such change occurs and (ii) the location at which Executive performed his principal duties for the Company immediately prior to the date on which such change occurs; or

(c) any material breach by the Company of this Agreement or any other material agreement between the Company and Executive.

4.4 Death or Disability. This Agreement shall terminate upon Executive's death or disability. As used in this Agreement, the determination of "disability" shall occur when Executive, due to a physical or mental disability, for a period of 60 consecutive days, or 120 days in the aggregate whether or not consecutive, during any 360-day period, is unable to perform the services contemplated under this Agreement. A determination of disability shall be made by a physician satisfactory to both Executive and the Company; provided, that, if Executive and the Company do not agree on a physician, Executive and the Company shall each select a physician and these two together shall select a third physician, whose determination as to disability shall be binding on all parties.

4.5 Termination by Executive Without Good Reason or Termination by the Company Without Cause. At the election of Executive without Good Reason or by the Company without Cause, upon not less than thirty (30) days' prior written notice to the other party.

## 5. Effect of Termination.

5.1 Payments Upon Termination for Any Reason. In the event Executive's employment terminates pursuant to Section 4, the Company shall pay to Executive (or Executive's estate or legal representative, if applicable), on the date of Executive's termination of employment with the Company (or as soon thereafter as is practicable, consistent with applicable law and the terms of any deferred compensation plan or agreement), the compensation and benefits under Sections 3.1, 3.4 and 3.5 that are accrued and unpaid through such termination date (including, without limitation, an amount equal to all accrued but unused vacation pay and unreimbursed expenses). In the event of termination of Executive's employment by Executive by reason of non-renewal of the Agreement Term pursuant to Sections 1 and 4.1, the Company for Cause pursuant to Section 4.2, by reason of Executive's death or disability pursuant to Section 4.4, or by Executive without Good Reason pursuant to Section 4.5, Executive shall not receive any compensation or benefits other than as expressly stated in this Section 5.1 and as otherwise required by law.

5.2 Termination by the Company Without Cause, by the Company by Reason of Non-Renewal of Agreement Term, or by Executive for Good Reason. Subject to Section 5.3 below, in addition to the payments and provisions under Section 5.1, in the event of termination of Executive's employment by the Company by reason of non-renewal of the Agreement Term pursuant to Sections 1 and 4.1, by Executive for Good Reason pursuant to Section 4.3, or by the Company without Cause pursuant to Section 4.5, provided that Executive executes a release of claims substantially in the form attached hereto as Exhibit A (the "Release"), which Release must be effective and irrevocable prior to the sixty (60<sup>th</sup>) day following the termination of the Executive's employment (the "Review Period"), the Company shall provide Executive with the following:

(a) twelve (12) months of Executive's base salary in effect at the time of termination of employment, payable according to the Company's payroll commencing on the first payroll date following the date the Release is effective and irrevocable (the "Payment Date"), subject to compliance with Sections 5.5 and 12.6; and

(b) the Company will, for a period of twelve (12) months following Executive's termination from employment, continue Executive's participation in the Company's group health plan and dental plan and shall pay that portion of the premiums that the Company paid on behalf of Executive and his dependents during Executive's employment, provided, however, that if the Company's health insurance plan and/or dental plan does not permit such continued participation in such plan after Executive's termination of employment, then the Company shall pay that portion of the premiums associated with COBRA continuation coverage that the Company paid on behalf of Executive and his dependents during Executive's employment including any administrative fee, on Executive's behalf for such twelve-month period; and provided, further, that if Executive becomes employed with another employer during the period in which continued health insurance and/or dental insurance is being provided pursuant to this Section, the Company shall not be required to continue such health and dental benefits, or if applicable, to pay the costs of COBRA, if Executive becomes covered under a health insurance plan of the new employer. (For purposes of this Section 5.2(b), the term "Executive" shall include, to the extent applicable, Executive's spouse and any of Executive's dependents covered under the Company's group health plan and/or dental plan prior to his termination of employment.)

5.3 Termination in the Event of a Change in Control.

(a) In addition to the payments and provisions under Section 5.1 but in lieu of, and not in addition to, the payments required pursuant to Section 5.2 above, in the event Executive's employment with the Company is terminated by the Company by reason of non-renewal of the Agreement Term pursuant to Sections 1 and 4.1, by Executive for Good Reason pursuant to Section 4.3, or by the Company without Cause pursuant to Section 4.5, in any such case, in anticipation of and/or within twelve (12) months following a Change in Control (as defined below) provided that such Change in Control also qualifies as a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i) (where required to avoid the imposition of penalty taxes under Section 409A) and provided that Executive (or Executive's legal representative, if applicable) executes a Release and the Release becomes effective and irrevocable prior to the end of the Review Period, Executive shall be entitled to the following:

(i) a lump sum cash amount equal to twelve (12) months of Executive's base salary in effect at the time of Executive's termination, such payment to be made on the Payment Date, subject to compliance with Sections 5.5 and 12.6;

(ii) for up to twelve (12) months after Executive's date of termination, the Company shall continue Executive's participation in the Company's group health and dental plan and shall pay that portion of the premiums that the Company paid on behalf of Executive and his dependents during Executive's employment; provided, however, that if the Company's health insurance plan and/or dental insurance plan does not permit Executive's continued participation in such plan after his termination of employment, then the Company shall pay that portion of the premiums associated with COBRA continuation coverage that the Company paid on behalf of Executive and his dependents during Executive's employment including administrative fees, on Executive's behalf for so long as COBRA continuation coverage is available, up to twelve (12) months; and provided, further, that if Executive becomes employed with another employer during the period in which continued health insurance and/or dental insurance is being provided pursuant to this Section, the Company shall not be required to continue the relevant benefits, or if applicable, to pay the relevant costs of COBRA, if Executive becomes covered under a health insurance plan and/or dental plan of the new employer. (For purposes of this Section 5.3(a)(ii), the term "Executive" shall include, to the extent applicable, Executive's spouse and any of Executive's dependents covered under the Company's group health plan and/or dental plan prior to his termination of employment.)

(b) As used herein, “Change in Control” shall occur or be deemed to occur if any of the following events occur:

(i) any sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all

of the assets of the Company; or

(ii) any consolidation or merger of the Company (including, without limitation, a triangular merger) where the shareholders of the Company immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own, directly or indirectly, shares representing in the aggregate more than fifty percent (50%) of the combined voting power of all the outstanding securities of the corporation issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any); or

(iii) a third person, including a “person” as defined in Section 13(d)(3) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) (but other than (x) the Company, (y) any employee benefit plan of the Company, or (z) investors purchasing equity securities of the Company pursuant to a financing or a series of financings approved by the Board of Directors of the Company) becomes the beneficial owner (as defined in Rule 13d-3 under the Exchange Act) directly or indirectly, of Controlling Securities (as defined below). “Controlling Securities” shall mean securities representing 25% or more of the total number of votes that may be cast for the election of the directors of the Company.

#### 5.4 Effect of Termination on Stock Options and Other Equity Compensation

(a) In the event of Executive’s termination by Executive by reason of non-renewal of the Agreement Term pursuant to Sections 1 and 4.1, by the Company for Cause pursuant to Section 4.2, or by Executive without Good Reason pursuant to Section 4.5, all unvested stock options and other equity-based awards granted to Executive before and after the date of this Agreement shall be immediately forfeited upon the effective date of such termination of employment or as otherwise provided in the award agreement; provided, that, Executive shall have until the earlier of expiration date of the option or ninety (90) days from the date of termination of Executive to exercise all vested options unless the stock plan pursuant to which the option is granted requires earlier termination in connection with a liquidation or sale of the Company.

(b) In the event of Executive’s termination by the Company by reason of non-renewal of the Agreement Term pursuant to Sections 1 and 4.1, by Executive for Good Reason pursuant to Section 4.3, or by the Company without Cause pursuant to Section 4.5, and provided that Executive (or Executive’s legal representative, if applicable) executes a Release and the Release becomes effective and irrevocable prior to the end of the Review Period, that number of Executive’s unvested stock options and other equity-based awards that would otherwise have vested from the effective date of Executive’s termination to the first anniversary of such date shall vest as of the date the Release is effective and irrevocable and Executive (or Executive’s estate or legal representative, if applicable) shall have until the earlier of the expiration date of the option or one (1) year from the date of termination of Executive’s employment to exercise all vested options unless the stock plan pursuant to which the option is granted requires earlier termination in connection with a liquidation or sale of the Company.

(c) In the event Executive’s employment with the Company is terminated by the Company by reason of non-renewal of the Agreement Term pursuant to Sections 1 and 4.1, by Executive for Good Reason pursuant to Section 4.3, or by the Company without Cause pursuant to Section 4.5, in any such case, in anticipation of and/or within twelve (12) months following a Change in Control, in lieu of the acceleration provided for pursuant to Section 5.4(b) above, provided that Executive (or Executive’s legal representative, if applicable) executes a Release and the Release becomes effective and irrevocable prior to the end of the Review Period, to the extent vesting and acceleration will not result in a violation of Section 409A, all of Executive’s unvested stock options and other equity-based awards then in effect shall vest as of the date the Release is effective and irrevocable and Executive (or Executive’s estate or legal representative, if applicable) shall have until the earlier of the expiration date of the option or one (1) year from the date of termination of Executive’s employment to exercise all vested options unless the stock plan pursuant to which the option is granted requires earlier termination in connection with a liquidation or sale of the Company.

(d) In the event Executive's employment with the Company is terminated by reason of disability pursuant to Section 4.4, all unvested stock and stock options granted to Executive before and after the date of this Agreement shall be immediately forfeited upon the effective date of such termination of employment or as otherwise provided in the option agreement; provided, that, Executive shall have until the earlier of the expiration date of the option or one (1) year from the date of termination of Executive's employment to exercise all vested options unless the stock plan pursuant to which the option is granted requires earlier termination in connection with a liquidation or sale of the Company.

5.5 Review Period. In the event that the Review Period begins in one taxable year of the Executive and ends in a later taxable year, any payments contingent upon Executive's execution without revocation of the Release prior to the end of the Review Period will commence to be paid (or as applicable, made in full) on the first payroll date in the later taxable year. In no event will any payments be made or commence to be paid later than the ninetieth (90th) day following the Executive's date of termination, subject to compliance with Section 12.6 herein.

5.6 Limitation on Benefits. The Company will make the payments under this Agreement without regard to whether the deductibility of such payments (or any other payments or benefits) would be limited or precluded by Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and without regard to whether such payments would subject Executive to the federal excise tax levied on certain "excess parachute payments" under Section 4999 of the Code (the "Excise Tax"); provided, however, that if the Total After-Tax Payments (as defined below) would be increased by the reduction or elimination of any payment and/or other benefit (including the vesting of the options) under this Agreement, then the amounts payable under this Agreement will be reduced or eliminated as follows, if possible: (i) first, by reducing or eliminating any cash payments or other benefits (other than the vesting of the options) and (ii) second, by reducing or eliminating the vesting of that options that occurs as a result of such Change in Control (as provided above), to the extent necessary to maximize the Total After-Tax Payments. The Company's independent, certified public accounting firm (the "Accounting Firm") will determine whether and to what extent payments or vesting under this agreement are required to be reduced in accordance with the preceding sentence. For purposes of this Agreement, "Total After-Tax Payments" means the total of all "parachute payments" (as that term is defined in Section 280G(b)(2) of the Code) made to or for the benefit of Executive (whether made under the Agreement or otherwise) by the Company or any of its affiliates, after reduction for all applicable federal state and local income taxes, employment, social security and Medicare taxes, the imposition of the Excise Tax and all other taxes, determined by applying the highest marginal rate under Section 1 of the Code and under state and local laws which applied (or is likely to apply) to the Employee's taxable income for the tax year in which the transaction which causes the application of Section 280G of the Code occurs, or such other rate(s) as the Accounting Firm determines to be likely to apply to the Executive in the relevant tax year(s) in which any of the parachute payments is expected to be made) than if the Employee received all of the parachute payments. The Company agrees to pay for all costs associated with the Accounting Firm and the determination of the payments or vesting required to be reduced and for the avoidance of doubt, shall not be required to pay any taxes, penalties, interest or other expenses to which Executive may be subject. If it is ultimately determined (by IRS private letter ruling or closing agreement, court decision or otherwise) that Executive's parachute payments were reduced by too much or by too little in order to accomplish the purpose of this Section 5.6, the Executive and the Company shall promptly cooperate to correct such underpayment or overpayment in a manner consistent with the purpose of this Section 5.6.

5.7 Withholdings. Payments made under this Section 5 shall be subject to applicable federal, state and local taxes and withholdings. If the payment of any COBRA or health insurance premiums would otherwise violate the nondiscrimination rules or cause the reimbursement of claims to be taxable under the Patient Protection and Affordable Care Act of 2010, together with the Health Care and Education Reconciliation Act of 2010 (collectively, the “Act”) or Section 105(h) of the Code, the Company paid premiums shall be treated as taxable payments and be subject to imputed income tax treatment to the extent necessary to eliminate any discriminatory treatment or taxation under the Act or Section 105(h) of the Code.

6. Notices. All notices, requests, consents and other communications hereunder will be in writing, will be addressed, if to the Company, at its principal corporate offices to the attention of the Legal Department, and if to Executive, at his address set forth on the signature page hereto or the personnel records of the Company (as applicable), or in either case, such other address as a party may designate by notice hereunder, and will be either (i) delivered by hand, (ii) sent by overnight courier, or (iii) sent by registered or certified mail, return receipt requested, postage prepaid. All notices, requests, consents and other communications hereunder will be deemed to have been given either (i) if by hand, at the time of the delivery thereof to the receiving party at the address of such party set forth above, (ii) if sent by overnight courier, on the next business day following the day such notice is delivered to the courier service, or (iii) if sent by registered or certified mail, on the fifth business day following the day such mailing is made.

7. Absence of Restrictions. Executive represents and warrants that Executive is not bound by any employment contracts, restrictive covenants or other restrictions that prevent him from entering into employment with, or carrying out his responsibilities for, the Company, or which are in any way inconsistent with any of the terms of this Agreement. Executive further represents that, except as Executive has previously disclosed or described to the Company, Executive is not bound by the terms of any agreement with any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of his employment with the Company, to refrain from competing, directly or indirectly, with the business of such previous employer or any other party, or to refrain from soliciting employees, customers or suppliers of such previous employer or other party. Executive further represents that he will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others.

8. Entire Agreement. This Agreement constitutes the entire agreement between the parties and supersedes all prior agreements and understandings, whether written or oral relating to the subject matter of this Agreement, with the exception of the Invention, Non-Disclosure, Non-Competition and Non-Solicitation Agreement by and between the Company and Executive. Notwithstanding the foregoing, the parties to this Agreement acknowledge that stock options and other equity awards may be granted by the Company to Executive under and pursuant to the Intercept Pharmaceuticals, Inc. 2012 Equity Incentive Plan and any amendments thereto, as well as any additional plans, and the award agreements related to such plans.

9. Amendment. This Agreement may be amended or modified only by a written instrument executed by both the Company and Executive.

10. Governing Law; Consent to Jurisdiction. This Agreement shall be construed, interpreted and enforced in accordance with the laws of the State of New York without regard to conflict of law principles. Any action, suit or other legal proceeding arising under or relating to any provision of this Agreement shall be commenced only in a court of the State of New York (or, if appropriate, a federal court located within the State of New York), and the Company and Executive each consents to the jurisdiction of such a court. THE COMPANY AND EXECUTIVE EACH HEREBY IRREVOCABLY WAIVE ANY RIGHT TO A TRIAL BY JURY IN ANY ACTION, SUIT OR OTHER LEGAL PROCEEDING ARISING UNDER OR RELATING TO ANY PROVISION OF THIS AGREEMENT .

11. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation or other entity with which, or into which, the Company may be merged or which may succeed to the Company's assets or business, provided, however, that the obligations of Executive are personal and shall not be assigned by him. Notwithstanding the foregoing, if Executive dies the compensation and benefits stated in this Agreement will be paid to his beneficiary or his estate if no beneficiary.

12. Miscellaneous .

12.1 No Waiver. No delay or omission by the Company in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given on any one occasion shall be effective only in that instance and shall not be construed as a bar or waiver of any right on any other occasion.

12.2 Captions. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

12.3 Severability. In case any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

12.4 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. This Agreement may be delivered by facsimile, and facsimile signatures shall be treated as original signatures for all applicable purposes.



12.5 Blue Pencil. To the extent that any provision herein or in any plan of nonqualified deferred compensation that this document is a part of contravenes the requirements of Code Section 409A or the regulations thereunder, such provision shall be appropriately modified in accordance with available IRS guidance (including without limitation IRS Notice 2010-6 and related guidance) so that Executive is not subject to the adverse effects of Code Section 409A but will nevertheless retain, to the extent possible, the economic benefit of the provision.

12.6 Section 409A: Withholding.

12.6.1 The payments under this Agreement are intended either to be exempt from Section 409A of the Code under the short-term deferral, separation pay, or other applicable exception, or to otherwise comply with Section 409A. The parties agree that this Agreement shall be administered in a manner consistent with such intent. For purposes of Section 409A, all payments under this Agreement shall be considered separate payments. If any amount or benefit payable to the Executive under this Agreement upon a “termination of employment” is determined by the Company to constitute a “deferral of compensation” for purposes of Section 409A (after taking into account any applicable exceptions), such amount or benefit shall not be paid or provided until the Executive has also experienced a “separation from service” from the Company within the meaning of Section 409A. Notwithstanding any provision to the contrary, to the extent Executive is considered a specified employee under Section 409A and would be entitled during the six-month period beginning on Executive’s separation from service to a payment that is not otherwise excluded under Section 409A, such payment will not be made until the earlier of the six-month anniversary of Employee’s separation from service or death; provided that the first payment made after the delay shall include all amounts that would have been paid earlier but for such six (6) month delay. At the request of the Executive, the Company shall set aside those payments that would otherwise be made in such six-month period in a trust that is in compliance with Rev. Proc. 92-64.

12.6.2 If an expense reimbursement or provision of in-kind benefit provided to the Executive under this Agreement is not exempt from Section 409A of the Code, the following rules apply: (i) in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred; (ii) the amount of reimbursable expenses incurred or provision of in-kind benefits in one tax year shall not affect the expenses eligible for reimbursement or the provision of in-kind benefits in any other tax year; and (iii) the right to reimbursement for expenses or provision of in-kind benefits is not subject to liquidation or exchange for any other benefit.

12.6.3 The parties agree to negotiate in good-faith the amendment of this Agreement, as necessary, to avoid any violations of Section 409A in a manner that preserves the original intent of the parties to the extent reasonably possible. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by Executive on account of non-compliance with Section 409A.

12.6.4 All compensatory payments under this Agreement are subject to any required tax or other withholdings.

12.7 Interpretation. References to decisions by the Company will be made by the Board or the applicable Board committee.

[signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year set forth above.

**THE COMPANY:**

**INTERCEPT PHARMACEUTICALS, INC.**

By: /s/ Mark E. Pruzanski  
Name: Mark E. Pruzanski, M.D.  
Title: President and Chief Executive Officer

Date: February 15, 2017

**EXECUTIVE:**

By: /s/ Jerome Durso  
Name: Jerome Durso

Date: February 15, 2017

Address for Notice Purposes:

[Last address in books and records of the Company]

Exhibit A

RELEASE OF CLAIMS <sup>[1]</sup>

**FOR AND IN CONSIDERATION OF** the payments and benefits (the “**Separation Benefits**”) to be provided to me in connection with the separation of my employment, in accordance with the Employment Agreement between Intercept Pharmaceuticals, Inc. (the “**Company**”) and me dated February 15, 2017 (the “**Agreement**”), which Separation Benefits are conditioned on my signing this Release of Claims (“**Release**”) and which I will forfeit unless I execute and do not revoke this Release of Claims, I, on my own behalf and on behalf of my heirs and estate, voluntarily, knowingly and willingly release and forever discharge the Company, its subsidiaries, affiliates, parents, and, in their capacities as such, stockholders, together with each of those entities’ respective officers, directors, stockholders, employees, agents, fiduciaries and administrators, each in their capacities as such (collectively, the “**Releasees**”) from any and all claims and rights of any nature whatsoever which I now have or in the future may have against them up to the date I execute this Release, whether known or unknown, suspected or unsuspected. This Release includes, but is not limited to, any rights or claims relating in any way to my employment relationship with the Company or any of the other Releasees or the termination thereof, any contract claims (express or implied, written or oral), including, but not limited to, the Agreement, or any rights or claims under any statute, including, without limitation, the Americans with Disabilities Act, the Age Discrimination in Employment Act, the Older Workers’ Benefit Protection Act, the Rehabilitation Act of 1973 (including Section 504 thereof), Title VII of the 1964 Civil Rights Act, the Civil Rights Act of 1866 (42 U.S.C. § 1981), the Civil Rights Act of 1991, the Equal Pay Act, the National Labor Relations Act, the Worker Adjustment and Retraining Notification Act, the Family Medical Leave Act, the Lilly Ledbetter Fair Pay Act, the Genetic Information Non-Discrimination Act, the New York State Human Rights Law, the New York City Human Rights Law, and the Employee Retirement Income Security Act of 1974, all as amended, and any other federal, state or local law. This Release specifically includes, but is not limited to, any claims based upon the right to the payment of wages, incentive and performance compensation, bonuses, equity grants, vacation, pension benefits, 401(k) Plan benefits, stock benefits or any other employee benefits, or any other rights arising under federal, state or local laws prohibiting discrimination and/or harassment on the basis of race, color, age, religion, sexual orientation, religious creed, sex, national origin, ancestry, alienage, citizenship, nationality, mental or physical disability, denial of family and medical care leave, medical condition (including cancer and genetic characteristics), marital status, military status, gender identity, harassment or any other basis prohibited by law.

As a condition of the Company entering into this Release, I further represent that I have not filed against the Company or any of the other Releasees, any complaints, claims or lawsuits with any arbitral tribunal, administrative agency, or court prior to the date hereof, and that I have not transferred to any other person any such complaints, claims or lawsuits. I understand that by signing this Release, I waive my right to any monetary recovery in connection with a local, state or federal governmental agency proceeding and I waive my right to file a claim seeking monetary damages in any arbitral tribunal, administrative agency, or court. This Release does not: (i) prohibit or restrict me from communicating, providing relevant information to or otherwise cooperating with the U.S. Equal Employment Opportunity Commission or any other governmental authority with responsibility for the administration of fair employment practices laws (including with respect to SEC Whistleblowing) regarding a possible violation of such laws or responding to any inquiry from such authority, including an inquiry about the existence of this Release or its underlying facts, or (ii) require me to notify the Company of such communications or inquiry. Furthermore, notwithstanding the foregoing, this Release does not include and will not preclude: (a) rights or claims to vested benefits under any applicable retirement and/or pension plans; (b) rights under the Consolidated Omnibus Budget Reconciliation Act of 1985 (“COBRA”); (c) claims for unemployment compensation; (d) rights to defense and indemnification or under the Company’s directors’ and officers’ liability insurance, if any, from the Company for actions or inactions taken by me in the course and scope of my employment with the Company and its parents, subsidiaries and/or affiliates; (e) any rights I may have to obtain contribution as permitted by law in the event of entry of judgment against the Company as a result of any act or failure to act for which I and the Company are held jointly liable; (f) any rights to vested equity that vested prior to or because of the termination of my employment and rights as a stockholder; and/or (g) any actions to enforce the Agreement.

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[1] The Executive agrees that the Company may revise this release to satisfy the purpose of providing as full a release of claims (subject to payment of any benefits provided on the applicable termination of employment) as may be legally permissible. The Company may revise it to reflect changes in law for releases and may add language for ADEA compliance.

For the avoidance of doubt, notwithstanding anything to the contrary, this Release does not limit my right to receive an award from any governmental agency for information provided to the governmental agency. However, by executing this Release, I hereby waive the right to recover any damages, compensation or monetary award from the Company in any lawsuit or any proceeding before any governmental agency that arises out of alleged facts or circumstances on or before the effective date of this Release.

I acknowledge that, in signing this Release, I have not relied on any promises or representations, express or implied, other than those that are set forth expressly herein or in the Agreement and that are intended to survive separation from employment, in accordance with the terms of the Agreement.

**Nondisclosure: Continuing Obligations** - I understand and agree that, to the extent permitted by law, the terms and contents of this Release (as modified before signature) and the contents of the negotiations and discussions resulting in this Release shall be maintained as confidential by me and must not be disclosed to anyone other than a member of my immediate family, my attorney, accountant or other advisor (and, even as to such a person, only if the person agrees to honor this confidentiality requirement) except to the extent required by federal or state law or as otherwise agreed to in writing by the Company. I acknowledge and reaffirm my obligation to keep confidential and not disclose any and all non-public information concerning the Company that I acquired during the course of my employment or other relationship with the Company, including any non-public information concerning the Company's business affairs, business prospects and financial condition, as is stated more fully in any Invention, Non-Disclosure, Non-Competition and Non-Solicitation Agreement and that I will comply with such agreement in all other respects.

The Company understands and agrees that the contents of the negotiations and discussions resulting in this Release shall be maintained as confidential and shall not be disclosed to any third parties, except to the extent required by federal or state law or as otherwise agreed to in writing with you.

**Mutual Non-Disparagement** – I understand and agree that I shall not make any false, disparaging or derogatory statements to any person or entity, including any media outlet, industry group or financial institution, regarding the Company, or any of the other Releasees or about the Company’s business affairs and financial condition. The Company confirms that it has instructed the members of its Board of Directors and its current executive officers to not make any false, disparaging or derogatory statements to any person or entity, including any media outlet, industry group or financial institution, regarding me, my employment with the Company, or my departure from the Company. Notwithstanding the foregoing, nothing herein prevents either the Releasees or me from making truthful disclosures to any governmental entity or to enforce this Letter Agreement and the Release. For the avoidance of doubt, nothing in this agreement prohibits me from communicating with a government agency, regulator or legal authority concerning any possible violations of federal or state law or regulation. Nothing in this agreement, however, authorizes the disclosure of information I obtained through a communication that was subject to the attorney-client privilege, unless disclosure of the information would otherwise be permitted by an applicable law or rule.

**Return of Company Property** - I confirm that I have returned to the Company in good working order all Company-owned keys, files, records (and copies thereof), equipment (including computer hardware, software and printers, wireless handheld devices, cellular phones, tablets, smartphones, etc.), Company identification, the Company proprietary and confidential information, and any other Company-owned property in my possession or control and I have left intact with, or delivered intact to, the Company all electronic Company documents and internal and external websites, including those that I developed or helped to develop during my employment, and that I have thereafter deleted, and destroyed any hard copies of, all electronic files relating to the Company that are in my possession or control, including any that are located on any of my personal computers or external or cloud storage. I further confirm that I have cancelled all accounts for my benefit, if any, in the Company’s name including, but not limited to, credit cards, telephone charge cards, cellular phone and/or wireless data accounts and computer accounts. Notwithstanding the foregoing, you shall be permitted to retain your contacts and calendars and personal correspondence and any documents or data related to your compensation or reasonably needed for tax preparation purposes.

**Final Compensation** – I acknowledge that I have received payment in full for all services rendered in conjunction with my employment by the Company, including payment for all wages, bonuses, and equity for any period before the date of this Release (other than any current salary and benefits due in the ordinary course in a final paycheck or thereafter), and that no other compensation is owed to me, except as provided in the applicable provisions of Section 5 of the Agreement; *provided* that nothing herein shall affect any claims of entitlement I may have to vested benefits under any 401(k) plan or other ERISA-covered benefit plan (excluding severance) provided by the Company.

**Cooperation** – I agree to cooperate with, provide assistance to, and make myself reasonably available to the Company and its legal counsel in connection with any litigation (including arbitration or administrative hearings) or investigation or examination relating to the Company or any of its current or former employees, in which, in the reasonable judgment of the Company or its counsel, my assistance or cooperation is needed due to my personal involvement in or knowledge about the circumstances to which the litigation or investigation relates. I will, when the Company or its counsel requests, provide testimony, be available for interviews or other assistance and travel at the Company’s reasonable request in order to fulfill this obligation. In connection with such litigation or investigation (a “Matter”), the Company will use its best efforts to accommodate my schedule, will provide me with as much notice as possible in advance of the times during which my cooperation or assistance is needed, and will compensate me (on a Matter-by-Matter basis) at the hourly rate of \$250 for any time exceeding four (4) hours, with such compensation payable from the first minute if such time exceeds four (4) hours in the aggregate spent cooperating with the Company for such Matter, and will reimburse me for any reasonable travel and lodging expenses incurred in connection with such matters (at a level of travel consistent with my travel while employed by the Company) and the reasonable fees of any independent counsel retained by me if I reasonably believe separate counsel to be appropriate. I agree not to assist or provide information to any adverse party in any litigation against the Company or any of its current or former employees, except as required under law or formal legal process, unless I provide advance notice to the Company at least 10 days before such assistance or provision of information (or, if I am so required to assist or provide such information within less than 10 days of receipt of such requirement, after I provide timely advance notice to the Company) to allow the Company to take legal action with respect to the matter. Finally, I will undertake to satisfy requests for information from the Company with respect to the above undertaking. *Nothing in this Release is intended to restrict or preclude me from, or otherwise influence me in, testifying fully and truthfully in legal, administrative, or any other proceedings involving the Company, as required by law or formal legal process.*

**Tax Provision** – I acknowledge that I am not relying upon advice or representation of the Company with respect to the tax treatment of any of the payments or benefits provided by the Company. The benefits provided to me are intended to be exempt from or compliant with Section 409A of the Internal Revenue Code of 1986. *The Company makes no representation or warranty and shall have no liability to me or to any other person if any of the provisions of the Agreement or this Release are determined to constitute deferred compensation subject to Section 409A but not to satisfy an exemption for, or the conditions of, that section.* All payments stated will be reduced by all applicable taxes and withholdings.

**Nature of Agreement** – I understand and agree that this Release is a severance agreement and does not constitute an admission of liability or wrongdoing on the part of the Company.

**Voluntary Assent** – I affirm that no other promises or agreements of any kind have been made to or with me by any person or entity whatsoever to cause me to sign this Release, other than as reflected in the Agreement and that I fully understand the meaning and intent of the Release. I acknowledge that, in signing this Release, I have not relied on any promises or representations, express or implied, other than those that are set forth expressly herein or in the Agreement and that are intended to survive separation from employment, in accordance with the terms of the Agreement. I further state and represent that I have carefully read this Release, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof, and sign my name of my own free act.

**Validity**— Should any provision of this Release be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this Release.

I further acknowledge that:

- (1) I first received this Release on the date of the Agreement to which it is attached as Exhibit A;
- (2) I understand that, in order for this Release to be effective, I may not sign it prior to the date of my separation of employment with the Company but that if I wish to receive the Separation Benefits, I must sign and return this Release prior to the sixtieth (60<sup>th</sup>) day following my separation of employment;
- (3) I have carefully read and understand this Release;
- (4) The Company advised me to consult with an attorney and/or any other advisors of my choice before signing this Release;
- (5) I understand that this Release is **LEGALLY BINDING** and by signing it I give up certain rights;
- (6) I have voluntarily chosen to enter into this Release and have not been forced or pressured in any way to sign it;
- (7) I acknowledge and agree that the Separation Benefits are contingent on execution of this Release, which releases all of my claims against the Company and the Releasees, and I **KNOWINGLY AND VOLUNTARILY AGREE TO RELEASE** the Company and the Releasees from any and all claims I may have, known or unknown, in exchange for the benefits I have obtained by signing, and that these benefits are in addition to any benefit I would have otherwise received if I did not sign this Release;
- (8) I have seven (7) days after I sign this Release to revoke it by notifying the Company in writing. The Release will not become effective or enforceable until the seven (7) day revocation period has expired;
- (9) This Release includes a **WAIVER OF ALL RIGHTS AND CLAIMS** I may have under the Age Discrimination in Employment Act of 1967 (29 U.S.C. §621 *et seq.* ); and
- (10) This Release does not waive any rights or claims that may arise after this Release becomes effective, which is seven (7) days after I sign it, provided that I do not exercise my right to revoke this Agreement.



Intending to be legally bound, I have signed this Release as of the date written below.

Signature: \_\_\_\_\_  
Jerome Durso

\_\_\_\_\_ Date signed

**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: May 10, 2017

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

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## 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: May 10, 2017

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

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**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 March 31, 2017 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: May 10, 2017

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

Date: May 10, 2017

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

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