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 June 30, 2017

OR

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

For the transition period from to

Commission file number: 001-35668

INTERCEPT PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**22-3868459** **(I.R.S. Employer Identification Number)**
10 Hudson Yards, 37th FL **New York, NY** **(Address of Principal Executive Offices)**	**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 June 30, 2017, there were 25,099,921 shares of common stock, $0.001 par value per share, outstanding.

Intercept Pharmaceuticals, Inc.

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

FORWARD-LOOKING STATEMENTS

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

The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “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:

- the potential benefit and commercial potential of Ocaliva® (obeticholic acid, or OCA) in primary biliary cholangitis, or PBC, and our ability to maintain our regulatory approval of Ocaliva in PBC in the United States, Europe and other jurisdictions in which we have or may receive marketing authorization;
- the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;
- the timing of and our ability to obtain regulatory approval of OCA in indications other than PBC and regulatory approval of any other product candidates 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, and in our subsequent periodic and current reports filed with the Securities and Exchange Commission, including those filed in this Quarterly Report on Form 10-Q. Those risk factors, together with any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

NON-GAAP FINANCIAL MEASURES

This Quarterly Report on Form 10-Q presents projected adjusted operating expense, which is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP, and should be considered in addition to, but not as a substitute for, operating expense that we prepare and announce in accordance with GAAP. We exclude certain items from adjusted operating expense, such as stock-based compensation and other non-cash items, that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. For the six months ended June 30, 2016, adjusted operating expense also excludes a one-time $45 million net expense for the settlement of a purported class action lawsuit. Other than the net class action lawsuit settlement amount, which is a one-time expense, we anticipate that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under GAAP. A reconciliation of projected non-GAAP adjusted operating expense to operating expense calculated in accordance with GAAP is not available on a forward-looking basis without unreasonable effort due to an inability to make accurate projections and estimates related to certain information needed to calculate, for example, future stock-based compensation expense. Management also uses adjusted operating expense to establish budgets and operational goals and to manage our company’s business. Other companies may define this measure in different ways. We believe this presentation provides investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information.

NOTE REGARDING TRADEMARKS

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

PART I

Item 1. FINANCIAL STATEMENTS

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except per share data)

	June 30, 2017 (Unaudited)	December 31, 2016 (Audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 62,031	$ 43,675
Investment securities, available-for-sale	488,274	645,710
Accounts receivable, net	13,230	9,126
Prepaid expenses and other current assets	15,025	9,354
Total current assets	578,560	707,865
Fixed assets, net	17,659	11,295
Inventory, net	2,682	2,279
Security deposits	16,844	17,814
Total assets	$ 615,745	$ 739,253
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses and other liabilities	$ 73,260	$ 65,551
Short-term interest payable	7,475	7,267
Short-term portion of deferred revenue	6,836	5,694
Total current liabilities	87,571	78,512
Long-term liabilities:		
Long-term debt	348,367	341,356
Long-term other liabilities	6,540	-
Long-term portion of deferred revenue	3,563	4,453
Total liabilities	446,041	424,321
Stockholders' equity:		
Preferred stock par value $0.001 per share; 5,000,000 shares authorized; none outstanding as of June 30, 2017 and December 31, 2016, respectively	-	-
Common stock par value $0.001 per share; 45,000,000 shares authorized; 25,099,921 and 24,819,918 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	25	25
Additional paid-in capital	1,456,878	1,426,168
Accumulated other comprehensive loss, net	(1,529)	(2,801)
Accumulated deficit	(1,285,670)	(1,108,460)
Total stockholders' equity	169,704	314,932
Total liabilities and stockholders' equity	$ 615,745	$ 739,253

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Condensed Consolidated Statements of Operations

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

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Revenue:				
Product revenue, net	$ 30,441	$ 75	$ 51,044	$ 75
Licensing revenue	446	5,445	891	5,891
Total revenue	30,887	5,520	51,935	5,966
Operating expenses:				
Cost of sales	279	-	376	-
Selling, general and administrative	66,925	48,715	128,007	144,580
Research and development	44,192	34,900	88,024	66,880
Total operating expenses	111,396	83,615	216,407	211,460
Operating loss	(80,509)	(78,095)	(164,472)	(205,494)
Other income (expense):				
Interest expense	(7,279)	-	(14,486)	-
Other income, net	1,224	796	2,464	1,521
	(6,055)	796	(12,022)	1,521
Net loss	$ (86,564)	$ (77,299)	$ (176,494)	$ (203,973)
Net loss per common and potential common share:				
Basic and diluted	$ (3.46)	$ (3.14)	$ (7.07)	$ (8.31)
Weighted average common and potential common shares outstanding:				
Basic and diluted	25,028	24,612	24,980	24,553

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Net loss	$ (86,564)	$ (77,299)	$ (176,494)	$ (203,973)
Other comprehensive loss:				
Unrealized gains (losses) on securities:				
Unrealized holding gains arising during the period	291	305	705	2,038
Reclassification for recognized losses on marketable investment securities during the period	-	29	-	(51)
Net unrealized gains on marketable investment securities	$ 291	$ 334	$ 705	$ 1,987
Foreign currency translation adjustments	362	(368)	567	(894)
Comprehensive loss	$ (85,911)	$ (77,333)	$ (175,222)	$ (202,880)

See accompanying notes to the condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (176,494)	$ (203,973)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	28,347	14,497
Amortization of investment premium	1,926	2,664
Amortization of deferred financing costs	694	-
Depreciation	1,874	1,544
Accretion of debt discount	6,317	-
Changes in operating assets:		
Prepaid expenses and other current assets	(5,671)	(9,501)
Accounts receivable	(4,104)	-
Inventory	(403)	-
Changes in operating liabilities:		
Accounts payable, accrued expenses and other current liabilities	7,709	(2,898)
Litigation settlement	-	55,000
Long-term other liabilities	6,540	-
Interest payable	208	-
Deferred revenue	252	1,790
Net cash used in operating activities	(132,805)	(140,877)
Cash flows from investing activities:		
Purchases of investment securities	(80,698)	(35,318)
Refund of security deposits	970	-
Sales of investment securities	236,913	242,117
Litigation settlement (restricted cash)	-	(45,000)
Purchases of equipment, leasehold improvements, and furniture and fixtures	(8,238)	(4,187)
Net cash provided by investing activities	148,947	157,612
Cash flows from financing activities:		
Proceeds from exercise of options, net	1,647	2,906
Net cash provided by financing activities	1,647	2,906
Effect of exchange rate changes	567	(682)
Net increase in cash and cash equivalents	18,356	18,959
Cash and cash equivalents – beginning of period	43,675	32,742
Cash and cash equivalents – end of period	$ 62,031	$ 51,701

See accompanying notes to the condensed consolidated financial statements.

INTERCEPT PHARMACEUTICALS, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Overview of Business

Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company") is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases, including primary biliary cholangitis ("PBC"), nonalcoholic steatohepatitis ("NASH"), primary sclerosing cholangitis ("PSC") and biliary atresia. Founded in 2002 in New York, Intercept now has operations in the United States, Europe and Canada.

2. Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All intercompany accounts and transactions have been eliminated. Certain information that is normally required by U.S. GAAP has been condensed or omitted in accordance with rules and regulations of the Securities and Exchange Commission ("SEC"). Operating results for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for any future period or for the year ending December 31, 2017. In the opinion of management, these unaudited condensed consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of these interim unaudited condensed consolidated financial statements.

These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2016, included in the Company's 2016 Annual Report on Form 10-K filed with the SEC.

Certain reclassifications have been made to prior period amounts in the Company's unaudited condensed consolidated statements of operations to conform to the current period presentation. The Company reclassified certain medical affairs costs of $6.5 million and $11.9 million from research and development expense to selling, general and administrative expense on the unaudited condensed consolidated statements of operations during the three and six months ended June 30, 2016.

Use of Estimates

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

3. Summary of Significant Accounting Policies

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

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 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 the adoption of ASU 2016-01 will have on its 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 and related disclosures.

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 consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. It is effective prospectively for the annual period ending December 31, 2018 and interim periods within that annual period. Early adoption is permitted. The Company is evaluating the impact of adoption of the standard on the consolidated financial statements and related disclosures, but does not expect it to have a significant impact.

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 June 30, 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 June 30, 2017 and 2016, the Company recorded licensing revenue of approximately $0.4 million and $5.4 million, respectively. During the six months ended June 30, 2017 and 2016, the Company recorded licensing revenue of approximately $0.9 million and $5.9 million, respectively.

5. Cash, Cash Equivalents and Investments

The following table summarizes the Company's cash, cash equivalents and investments as of June 30, 2017 and December 31, 2016:

	As of June 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$ 62,031	$ -	$ -	$ 62,031
Investment securities:				
Commercial paper	40,949	-	(11)	40,938
Corporate debt securities	423,948	13	(834)	423,127
U.S. government and agency securities	24,248	-	(39)	24,209
Total investments	489,145	13	(884)	488,274
Total cash, cash equivalents and investments	$ 551,176	$ 13	$ (884)	$ 550,305

	As of December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(In thousands)			
Cash and cash equivalents:				
Cash and money market funds	$ 43,675	$ -	$ -	$ 43,675
Investment securities:				
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 June 30, 2017, the Company held a total of one position that was 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 June 30, 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 June 30, 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 (Years)	June 30, 2017	December 31, 2016
		(In thousands)	
Office equipment and software	3	$ 4,927	$ 4,942
Leasehold improvements	Over life of lease	13,777	6,668
Furniture and fixtures	7	4,985	4,202
Subtotal		23,689	15,812
Less: accumulated depreciation		(6,030)	(4,517)
Fixed assets, net		$ 17,659	$ 11,295

7. Inventory, Net

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

	June 30, 2017	December 31, 2016
	(In thousands)	
Work-in-process	$ 2,586	$ 2,207
Finished goods	96	72
Inventory, net	$ 2,682	$ 2,279

8. Accounts Payable, Accrued Expenses and Other Liabilities

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

	June 30, 2017	December 31, 2016
	(In thousands)	
Accounts payable	$ 13,206	$ 6,722
Accrued contracted services	38,708	35,429
Accrued employee compensation	15,153	19,287
Other liabilities	6,193	4,113
Accounts payable, accrued expenses and other liabilities	$ 73,260	$ 65,551

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:

		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
		(In thousands)		
June 30, 2017				
Assets:				
Money market funds (included in cash and cash equivalents)	$ 15,275	$ 15,275	$ -	$ -
Available for sale securities:				
Commercial paper	40,938	-	40,938	-
Corporate debt securities	423,127	-	423,127	-
U.S. government and agency securities	24,209	-	24,209	-
Total financial assets:	$ 503,549	$ 15,275	$ 488,274	$ -
December 31, 2016				
Assets:				
Money market funds (included in cash and cash equivalents)	$ 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	$ 657,465	$ 11,755	$ 645,710	$ -

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

	Fair Value as of	
	June 30, 2017	December 31, 2016
	(In thousands)	
Due in one year or less	$ 415,254	$ 456,184
Due after 1 year through 5 years	73,020	189,526
Total investments in debt securities	$ 488,274	$ 645,710

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:

	June 30, 2017	December 31, 2016
	(In thousands)	
Long-term debt	$ 348,367	$ 341,356
Less current portion	-	-
Long-term debt outstanding	$ 348,367	$ 341,356

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 $113.2 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 $7.3 million and $0 for the three months ended June 30, 2017 and 2016, respectively, and $14.5 million and $0 for the six months ended June 30, 2017 and 2016, respectively, related to the Convertible Notes. Accrued interest on the Convertible Notes was approximately $7.5 million and $7.3 million as of June 30, 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 June 30, 2017, $11.0 million of debt issuance costs are recorded on the unaudited condensed consolidated balance sheet in Long-Term Debt, in accordance with ASU 2015-03. As of June 30, 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 $30.4 million and $75,000 for the three months ended June 30, 2017 and 2016, respectively, and $51.0 million and $75,000 for the six months ended June 30, 2017 and 2016, respectively. The Company also recorded $5.1 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 June 30, 2017 and December 31, 2016, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)			
Product revenue, net:				
U.S.	$ 27,876	$ 75	$ 47,653	$ 75
ex-U.S.	2,565	-	3,391	-
Total product revenue, net	$ 30,441	$ 75	$ 51,044	$ 75

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 number 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 six months ended June 30, 2017:

	Number of Shares (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (In thousands)
Outstanding at December 31, 2016	1,553	$ 117.80	7.4	$ 48,308
Granted	474	$ 113.51	-	$ -
Exercised	(81)	$ 22.72	-	$ -
Cancelled/forfeited	(62)	$ 143.74	-	$ -
Expired	(14)	$ 195.80	-	$ -
Outstanding at June 30, 2017	1,870	$ 119.40	7.6	$ 53,422
Expected to vest	1,870	$ 119.40	7.6	$ 53,422
Exercisable	893	$ 103.38	6.1	$ 45,280

As of June 30, 2017, there was approximately $63.3 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 2.7 years.

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

	Six Months Ended June 30,	
	2017	2016
Volatility	60.9 - 65.4%	60.7 - 62.4%
Expected term (in years)	6.0 - 9.9	3.2 - 10.0
Risk-free rate	1.8 - 2.4%	0.9 - 1.8%
Expected dividend yield	—%	—%

The following table summarizes the aggregate RSU and RSA activity during the six months ended June 30, 2017:

	Number of Awards	Weighted Average Fair Value
	(In thousands)	
Non-vested shares outstanding, December 31, 2016	381	$ 136.89
Granted	248	$ 113.57
Vested	(105)	$ 132.16
Forfeited	(27)	$ 133.75
Non-vested shares outstanding, June 30, 2017	497	$ 126.45

As of June 30, 2017, there was approximately $54.2 million of total unrecognized compensation expense related to unvested RSUs and RSAs, which is expected to be recognized over a weighted average period of 2.7 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)			
Selling, general and administrative	$ 9,915	$ 1,234	$ 18,889	$ 6,984
Research and development	4,371	3,019	9,458	7,513
Total stock-based compensation	$ 14,286	$ 4,253	$ 28,347	$ 14,497

13. Net Loss Per Share

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands, except per share amounts)			
Historical net loss per share				
Numerator:				
Net loss attributable to common stockholders	$ (86,564)	$ (77,299)	$ (176,494)	$ (203,973)
Denominator:				
Weighted average shares used in calculating net loss per share - basic and diluted	25,028	24,612	24,980	24,553
Net loss per share:				
Basic and diluted	$ (3.46)	$ (3.14)	$ (7.07)	$ (8.31)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(In thousands)			
Convertible Notes	2,316	-	2,316	-
Options	1,870	1,640	1,870	1,640
Restricted stock units	497	383	497	383
Total	4,683	2,023	4,683	2,023

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 the "Risk Factors" section of our Annual Report on Form 10-K and this Quarterly Report on Form 10-Q and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

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

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

OCA was approved in the United States in May 2016 for use in patients with primary biliary cholangitis, or PBC, under the brand name Ocaliva®. We commenced sales and marketing of Ocaliva 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. In May 2017, Health Canada granted a conditional approval for Ocaliva in PBC and we commenced our commercial launch. We also plan to file for marketing authorization for OCA in PBC 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. Overall, more than 2,400 healthy volunteers and patients with a broad array of non-viral liver diseases have been treated in clinical trials with OCA. 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 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 have also completed a Phase 2 clinical trial, known as the CONTROL trial, the goal of which was to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. We announced that this trial met its primary endpoint in July 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 July 2017, we announced top-line results of our Phase 2 AESOP trial in PSC which evaluated the effects of 24 weeks of treatment with varying doses of OCA compared to placebo. This trial achieved its primary endpoint, which we believe establishes a proof-of-concept of OCA in a second cholestatic liver disease. We plan to discuss these results with regulatory authorities to formulate our future development plans for OCA in PSC. 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 are 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, Europe and certain other target markets 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 Pharma Co., Ltd., or 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 six months ended June 30, 2017 and 2016 was approximately $176.5 million and $204.0 million, respectively. As of June 30, 2017, we had an accumulated deficit of approximately $1.3 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, Europe and other jurisdictions where it has received marketing approval;
- seek regulatory approval for and prepare to commercially launch Ocaliva for PBC in other target markets;
- 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

Results of the Phase 2 CONTROL trial

On July 31, 2017, we announced results from the Phase 2 CONTROL trial evaluating prospectively the lipid metabolic effects of OCA and concomitant statin administration in NASH patients with fibrosis or cirrhosis. The CONTROL trial met its primary objective by showing that newly initiated treatment with atorvastatin rapidly reversed OCA-associated increases in LDL to below baseline levels. Most of the effect was observed four weeks after initiation of the lowest available dose of atorvastatin and was sustained throughout the study period.

CONTROL is a 16-week double-blind, placebo-controlled, dose-ranging study of 84 NASH patients with fibrosis and compensated cirrhosis, followed by a two-year long-term safety extension, or LTSE, open label phase which is currently ongoing. Lipid changes were assessed every four weeks over the course of the double-blind phase. Details of the study design are as follows:

- Statin-naïve or washout patients were randomized to receive one of three doses of OCA (5 mg, 10 mg or 25 mg) or placebo.
- At week four, the lowest approved dose of atorvastatin (10 mg) was added in all patients.
- At week eight, patients were titrated to the next highest prescribed dose of atorvastatin (20 mg).
- At week 12, further titration of atorvastatin (up to 40 mg) was permitted at investigators’ discretion.

The study was designed to measure treatment differences within each group relative to baseline. The intent-to-treat, or ITT, analysis is shown below and includes all patients who received at least one dose of study medication.

At week four, mean LDL levels increased in each of the OCA treatment groups, while remaining relatively unchanged in the placebo group. The addition of 10 mg of atorvastatin rapidly reversed mean LDL to below baseline levels in all OCA treatment groups at the first assessed time point (week eight), and this effect was sustained through week 16. The observed mean LDL reductions in the OCA groups were approximately 40 – 45 mg/dL while placebo was 48 mg/dL.

(mg/dL)	Placebo (N=21)	OCA 5 mg (N=20)	OCA 10 mg (N=21)	OCA 25 mg (N=22)
Mean LDL at Baseline	118	135	122	126
Mean LDL at Week 4	113	153	141	158
Mean LDL at Week 8 (+atorvastatin 10 mg)	75	96	91	93
Mean LDL at Week 16 (+ atorvastatin 10 – 40 mg)	70	95	82	85
Mean LDL Change from Baseline at Week 16	-48	-40	-40	-45

The primary efficacy analysis was based on the efficacy evaluable population, defined as those patients who completed the double-blind phase and received all doses of OCA and atorvastatin (n=67). The overall results for the ITT population were similar to those in the efficacy evaluable population.

Lipid sub-fraction analysis showed that OCA-related increases in LDL were primarily driven by an increase in large buoyant LDL particles rather than small dense LDL particles. Changes in other lipid parameters were similar to those previously reported with OCA therapy in patients with NASH.

Mild to moderate pruritus was the most common adverse event in patients treated with OCA, occurring in 5%, 5%, 10% and 55% in placebo, 5 mg, 10 mg and 25 mg OCA groups, respectively. Two patients discontinued treatment in the 25 mg OCA treatment arm due to pruritus. Co-administration of atorvastatin and OCA was generally well tolerated and did not result in any unexpected safety observations.

The proportion of patients completing the double-blind period was similar across treatment groups (100%, 95%, 90% and 91% for placebo, OCA 5 mg, OCA 10 mg and OCA 25 mg, respectively). Of these patients, 77 of 79 (97%) chose to participate in the LTSE phase.

During the ongoing LTSE phase, there has been one patient death due to acute renal and liver failure. While we determined it could not be ruled out that this was possibly related to treatment, the principal investigator and the independent Data Safety Monitoring Committee determined the death was unlikely related to OCA.

Results of the Phase 2 AESOP trial

On July 31, 2017, we announced that the Phase 2 AESOP trial evaluating OCA for the treatment of patients with PSC met its primary endpoint. Patients who initiated OCA 5 mg with the option to titrate to 10 mg achieved a statistically significant reduction in alkaline phosphatase, or ALP, as compared to placebo ($p<0.05$).

AESOP is a 24-week, double-blind, placebo-controlled, dose-ranging trial evaluating the efficacy and safety of OCA compared to placebo in 77 patients with PSC, followed by a two-year LTSE open-label phase which is currently ongoing. Patients were randomized to one of three treatment groups: placebo, OCA 1.5 – 3 mg, and OCA 5 – 10 mg (with dose titration occurring at the 12-week midpoint). Approximately half the patients were receiving ursodiol treatment at baseline and continued on a stable dose during the trial. The primary endpoint of the study was the change in ALP relative to placebo at week 24 for the OCA 5 – 10 mg group. Results for the ITT population are shown below.

(U/L)	Placebo (N = 25)	OCA 1.5-3 mg (N = 25)	OCA 5-10 mg (N = 26)
Mean Baseline ALP	563	423	429
Least Squares (LS) Mean Change from Baseline in ALP at Week 12	-53	-57	-135*
LS Mean Change from Baseline in ALP at Week 24	-27	-105	-110*†
LS Mean Percent Change from Baseline at Week 24	+1%	-22%*	-22%*

* $p<0.05$
† Primary endpoint was ALP change for OCA 5-10 mg compared to placebo at week 24.

Pruritus is a common symptom of PSC and was the most common adverse event observed in the AESOP trial, occurring in 46%, 60% and 67% of patients in the placebo, OCA 1.5 – 3 mg and OCA 5 – 10 mg groups, respectively. Pruritus severity increased with OCA treatment in a dose-dependent manner. One (4%) patient in the OCA 1.5 – 3 mg group and three (12%) in the 5 – 10 mg group discontinued treatment due to pruritus compared to none with placebo.

Other treatment emergent adverse events were similar across all three arms and the proportion of patients completing the double-blind period was similar across treatment groups (84%, 76% and 81% for placebo, OCA 1.5-3 mg and OCA 5-10 mg, respectively). Of these patients, 59 of 61 (97%) chose to participate in the LTSE phase.

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 $30.4 million and $75,000 for the three months ended June 30, 2017 and 2016, respectively, and $51.0 million and $75,000 for the six months ended June 30, 2017 and 2016, respectively. We also recorded $5.1 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 June 30, 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 June 30, 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 $0.9 million and $5.9 million, respectively, in license revenue resulting from milestone payments and the amortization of the up-front payments under the collaboration agreement for the six months ended June 30, 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, Europe and certain other countries, 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 June 30, 2017 and 2016

The following table summarizes our results of operations for each of the three months ended June 30, 2017 and 2016, together with the changes in those items in dollars:

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Dollar Change
	(In thousands)		
Revenue:			
Product revenue, net	$ 30,441	$ 75	$ 30,366
Licensing revenue	446	5,445	(4,999)
Total revenue	30,887	5,520	25,367
Operating expenses:			
Cost of sales	279	-	279
Selling, general and administrative	66,925	48,715	18,210
Research and development	44,192	34,900	9,292
Total operating expenses	111,396	83,615	27,781
Operating loss	(80,509)	(78,095)	(2,414)
Other income (expense):			
Interest expense	(7,279)	-	(7,279)
Other income, net	1,224	796	428
	(6,055)	796	(6,851)
Net loss	$ (86,564)	$ (77,299)	$ (9,265)

Revenues

Product revenue, net was approximately $30.4 million and $75,000 for the three months ended June 30, 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 $27.8 million and $2.6 million in the United States and in ex-U.S. countries, respectively, during the three months ended June 30, 2017. For the three months ended June 30, 2017 and 2016, licensing revenue was approximately $0.4 million and $5.4 million, respectively, 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 $0.3 million and $0 for the three months ended June 30, 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 $66.9 million and $48.7 million for the three months ended June 30, 2017 and 2016, respectively. The $18.2 million net increase between periods is primarily due to an increase in personnel-related costs of $11.8 million to support our commercial and international initiatives, along with increased expenses of approximately $5.5 million in Ocaliva commercialization activities and market research and increases in indirect expenses (rent, travel and legal costs) of $0.9 million.

Research and development expenses

Research and development expenses were $44.2 million and $34.9 million for the three months ended June 30, 2017 and 2016, respectively, representing a net increase of $9.3 million. This net increase in research and development expense primarily reflects increases in OCA research and development activities of approximately $7.5 million and increases in INT-767 research and development activities of $1.7 million.

Interest expense

Interest expense was $7.3 million and $0 for the three months ended June 30, 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 $0.8 million in the three months ended June 30, 2017 and 2016, respectively. The $0.4 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 June 30, 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.

Comparison of the Six Months Ended June 30, 2017 and 2016

The following table summarizes our results of operations for each of the six months ended June 30, 2017 and 2016, together with the changes in those items in dollars:

	Six Months Ended June 30,		Dollar Change
	2017	2016	
	(In thousands)		
Revenue:			
Product revenue, net	$ 51,044	$ 75	$ 50,969
Licensing revenue	891	5,891	(5,000)
Total revenue	51,935	5,966	45,969
Operating expenses:			
Cost of sales	376	-	376
Selling, general and administrative	128,007	144,580	(16,573)
Research and development	88,024	66,880	21,144
Total operating expenses	216,407	211,460	4,947
Operating loss	(164,472)	(205,494)	41,022
Other income (expense):			
Interest expense	(14,486)	-	(14,486)
Other income, net	2,464	1,521	943
	(12,022)	1,521	(13,543)
Net loss	$ (176,494)	$ (203,973)	$ 27,479

Revenues

Product revenue, net was approximately $51.0 million and $75,000 for the six months ended June 30, 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 $47.7 million and $3.4 million in the United States and in ex-U.S. countries, respectively, during the six months ended June 30, 2017. For each of the six months ended June 30, 2017 and 2016, licensing revenue was approximately $0.9 million and $5.9 million, respectively, 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 $0.4 million and $0 for the six months ended June 30, 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 $128.0 million and $144.6 million for the six months ended June 30, 2017 and 2016, respectively. The $16.6 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 plus related legal expenses of $3.9 million in 2016, along with a decrease in consultant spend of $5.7 million. These decreases were partially offset by increased expenses of approximately $17.9 million in additional personnel-related costs to support our commercial and international initiatives, $17.8 million in Ocaliva commercialization activities and market research and indirect expenses (rent, travel and product-related legal costs) of $2.3 million.

Research and development expenses

Research and development expenses were $88.0 million and $66.9 million for the six months ended June 30, 2017 and 2016, respectively, representing a net increase of $21.1 million. This net increase in research and development expense primarily reflects increases in OCA research and development activities of approximately $20.1 million to support our development activities and an increase of $1.7 million of compensation-related costs, partially offset by a decrease in indirect costs of $0.7 million.

Interest expense

Interest expense was $14.5 million and $0 for the six months ended June 30, 2017 and 2016, respectively due to the issuance of the Convertible Notes, in July 2016.

Other income, net

Other income, net was $2.5 million and $1.5 million in the six months ended June 30, 2017 and 2016, respectively. The $1.0 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 six months ended June 30, 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 June 30, 2017, we had an accumulated deficit of $1.3 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 June 30, 2017, we had cash, cash equivalents and investment securities of $550.3 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:

	Six Months Ended June 30,	
	2017	2016
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (132,805)	$ (140,877)
Investing activities	148,947	157,612
Financing activities	1,647	2,906

Operating Activities. Net cash used in operating activities of approximately $132.8 million during the six months ended June 30, 2017 was primarily a result of our $176.5 million net loss, partially offset by a net increase in operating assets and liabilities of $4.5 million, $28.3 million in stock-based compensation, $6.3 million for accretion of the discount on our Convertible Notes, $1.9 million for the amortization of investment premium and $1.9 million of depreciation.

Net cash used in operating activities of $140.9 million during the six months ended June 30, 2016 was primarily a result of our $204.0 million net loss, offset by the add-back of non-cash expenses of $14.5 million for stock-based compensation, the amortization of investment premium of $2.7 million and a net increase in operating assets and liabilities of $44.4 million, including the $45.0 million net expense for settlement of the purported class action lawsuit.

Investing Activities. For the six months ended June 30, 2017, net cash provided by investing activities primarily reflects the sale of investment securities of $236.9 million, partially offset by the purchase of investment securities of $80.7 million and $8.2 million of capital expenditures related to the build out of our new corporate office.

For the six months ended June 30, 2016, net cash provided by investing activities primarily reflects the sale of investment securities of $242.0 million, partially offset by the $45.0 million for the settlement of the purported class action lawsuit, the purchase of investment securities of $35.3 million and $4.2 million of capital expenditures related to our offices.

Financing Activities. Net cash provided by financing activities in the six months ended June 30, 2017 consisted primarily of $1.6 million from the exercise of options to purchase common stock.

Net cash provided by financing activities in the six months ended June 30, 2016 consisted primarily of $2.9 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, Europe and other jurisdictions where it has received marketing approval, 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 may also engage in activities that involve potential in- or out-licensing of products or technologies or acquisitions of other products, technologies or businesses. We anticipate that we will need substantial additional funding in connection with our continuing operations.

As of June 30, 2017, we had $550.3 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, 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 six months ended June 30, 2016, adjusted operating expense also excludes a one-time $45 million net expense for the settlement of a purported class action lawsuit. Other than the net class action lawsuit settlement amount, which is a one-time expense, we anticipate that stock-based compensation expense will represent the most significant non-cash item that is excluded in adjusted operating expenses as compared to operating expenses under GAAP. 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, the European Union and other jurisdictions where it has received marketing approval;
- 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;
- conduct further assessments of OCA for use in PSC and potentially initiate, but not complete, additional clinical trials for OCA in PSC; 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 jurisdictions where it has received marketing approval;
- our ability to receive marketing approval of Ocaliva for PBC in countries where it has not received marketing approval 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 in the jurisdictions where it receives marketing approval;
- the progress, costs, results of and timing of our clinical development programs for OCA in PBC, NASH, PSC and other indications, such as the COBALT trial, the REGENERATE trial, the upcoming Phase 3 trial in NASH patients with cirrhosis or other trials we may conduct;
- 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 June 30, 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 June 30, 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 June 30, 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.

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.

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below and in our other filings are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see the "Forward-Looking Statements" section of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We are dependent on the successful commercialization of Ocaliva® (obeticholic acid or OCA), for primary biliary cholangitis, or PBC. To the extent Ocaliva is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

Ocaliva is our only drug that has been approved for sale and it has only been approved for the treatment of PBC in combination with ursodiol in adults with an inadequate response to ursodiol or as monotherapy in adults unable to tolerate ursodiol.

Our ability to generate profits from operations and become profitable will depend on the success of commercial sales of Ocaliva. However, the successful commercialization of Ocaliva in PBC is subject to many risks. We are currently undertaking our first commercial launch with Ocaliva in PBC, and there is no guarantee that we will be able to do so successfully. There are numerous examples of unsuccessful product launches and failures to meet expectations of market potential, including by pharmaceutical companies with more experience and resources than us.

The commercial success of Ocaliva depends on the extent to which patients, physicians and payers accept and adopt Ocaliva as a treatment for PBC, and we do not know whether our or others' estimates in this regard will be accurate. While we continue to conduct various activities, such as profiling of our customers, to better understand how physicians care for PBC patients, PBC is an orphan disease in which Ocaliva represented the first new therapy in approximately 20 years. As such, there is significant uncertainty in the degree of market acceptance Ocaliva will have in PBC. For example, if the patient population suffering from PBC is smaller than we estimate, or even if the patient population matches our estimate but Ocaliva is not widely accepted as a treatment for PBC, the commercial potential of Ocaliva will be limited. Physicians may not prescribe Ocaliva and patients may be unwilling to use Ocaliva if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, the use of Ocaliva in a non-trial setting may result in the occurrence of unexpected or a greater incidence of side effects, adverse reactions or misuse that may negatively affect the commercial prospects of Ocaliva. Furthermore, any negative development in any other development program of OCA or our failure to satisfy the post-marketing regulatory commitments and requirements to which we are or may become subject, including the completion of our Phase 4 COBALT trial, may adversely impact the commercial results and potential of Ocaliva.

As a result, we cannot foresee if Ocaliva will ever be accepted as a therapy in PBC that eventually results in revenues that can sustain operations. It may take the passage of a significant amount of time to generate sufficient revenues to sustain operations even if Ocaliva becomes accepted as a therapy in PBC. Furthermore, because Ocaliva is still undergoing regulatory review in a number of jurisdictions outside of the United States and the European Union, we may not be able to commercialize Ocaliva in PBC in such other jurisdictions, which may also limit our prospects. If the commercialization of Ocaliva for PBC is unsuccessful or perceived to be disappointing, the long-term prospects of Ocaliva and our company may be significantly harmed.

We have never been profitable. We expect to incur losses for the foreseeable future, and we may never achieve or sustain profitability.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses of $412.8 million, $226.4 million and $283.2 million for the years ended December 31, 2016, 2015 and 2014, respectively, and $176.5 million and $204.0 million for the six months ended June 30, 2017 and 2016, respectively. To date, we have financed our operations primarily through public and private securities offerings and payments received under our licensing and collaboration agreements. At June 30, 2017, we had $550.3 million in cash, cash equivalents and investment securities.

We have devoted substantially all of our resources to our development efforts relating to our product candidates, including conducting clinical trials of our product candidates, providing general and administrative support for these operations, protecting our intellectual property and engaging in activities to prepare for and commercially launch Ocaliva in PBC.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue to commercialize Ocaliva for PBC in jurisdictions where marketing approval has been received, seek regulatory approval for and prepare to commercially launch Ocaliva for PBC in jurisdictions without marketing approval, develop and seek regulatory approvals for OCA in nonalcoholic steatohepatitis, or 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 believe our prospects and ability to significantly grow revenues will be dependent on our ability to successfully develop and commercialize OCA for indications other than PBC such as NASH and primary sclerosing cholangitis, or PSC. As a result, we expect a significant amount of resources to continue to be devoted to our development programs for OCA.

As part of our product development activities, we anticipate that we will continue our Phase 4 COBALT trial of OCA in PBC, continue our Phase 3 clinical program of OCA in NASH, including the Phase 3 REGENERATE trial in non-cirrhotic NASH patients with liver fibrosis, and continue the development of OCA in PSC. We also expect to continue the development of OCA in additional diseases, such as biliary atresia, a rare pediatric disease characterized by deficient bile duct development for which we initiated a Phase 2 trial in OCA called CARE. Our overall development program for OCA in NASH is expected to include a number of trials, such as the Phase 2 clinical trial, referred to as the CONTROL trial, to assess the lipid metabolic effects of OCA and the effects of concomitant statin administration in NASH patients for which topline results were reported in July 2017. Furthermore, we completed a Phase 1 clinical trial for INT-767, an earlier stage product candidate, and we expect to incur further expenses as we continue to develop INT-767. Our expenses could increase if we are required by the U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates.

If OCA or any of our other product candidates fails in clinical trials or does not gain regulatory approval, or if they do not achieve market acceptance, we may never become profitable. Our net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We are currently advancing OCA through clinical development for multiple indications and other product candidates through various stages of clinical and preclinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive.

In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We have incurred and anticipate incurring significant expenses as we continue to commercialize Ocaliva in PBC. 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 facilities and infrastructure in the United States and abroad. We expect to incur additional costs associated with operating as a public company and further plan on expanding our operations in the United States, Europe and in certain other countries. We may also engage in activities that involve potential in- or out-licensing of products or technologies or acquisitions of other products, technologies or businesses.

As of June 30, 2017, we had $550.3 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, continued clinical development for OCA in PBC and NASH 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. Accordingly, we will continue to require substantial additional capital in connection with our continuing operations, including continuing our clinical development and commercialization activities, despite having started to generate revenues from product sales. Because successful development and commercialization of our products and product candidates is uncertain, we are unable to estimate the actual funds required to complete the research and development and commercialization of our products and product candidates.

Adjusted operating expense is a financial measure not calculated in accordance with U.S. generally accepted accounting principles, or GAAP. 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, such as the risks described in this “Risk Factors” section of this quarterly report on Form 10-Q, and our rapid growth and expansion, we currently cannot accurately or 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, the European Union and other jurisdictions where it has received marketing approval;
- 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 other 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;
- conduct further assessments of OCA for use in PSC and potentially initiate, but not complete, additional clinical trials for OCA in PSC; 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 jurisdictions where it has received marketing approval;
- our ability to receive marketing approval of Ocaliva for PBC in countries where it has not received marketing approval 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 in the jurisdictions where it receives marketing approval;
- the progress, costs, results of and timing of our clinical development programs for OCA in PBC, NASH, PSC and other indications, such as the COBALT trial, the REGENERATE trial, the upcoming Phase 3 trial in NASH patients with cirrhosis or other trials we may conduct;
- 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. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail our planned activities, including research and development programs and commercialization activities.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to seek additional funding 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. Additional funding may not be available to us on acceptable terms or at all.

The terms of any financing may adversely affect the holdings or the rights of our security holders. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest 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. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have a limited operating history as a commercial organization, which may make it difficult to predict our future performance, and we expect to continue to face a number of factors that may cause operating results to fluctuate.

We are a biopharmaceutical company with a limited operating history as a commercial entity. Prior to the commercial launch of Ocaliva for PBC in the United States in June 2016 and certain European countries in 2017, our operations were limited to developing our technology and undertaking preclinical studies and clinical trials of our product candidates and engaging in pre-commercial activities for Ocaliva in PBC. We do not have approval for any of our other product candidates.

While we commercially launched Ocaliva for PBC in the United States, Europe and certain other jurisdictions, we will need to conduct further activities to develop and cultivate a sustainable market for our drug in this orphan disease. These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully develop a market. For example, we will need to conduct significant sales and marketing activities in jurisdictions where Ocaliva receives marketing approval. In the event we are unable to effectively develop and maintain a market for Ocaliva in PBC, our ability to effectively commercialize Ocaliva would be limited, and we would not be able to generate product revenues successfully.

Furthermore, our financial condition and operating results have varied significantly in the past and are expected to continue to significantly fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- any delays in regulatory review and approval of our product candidates in clinical development;

- delays in the commencement, enrollment and timing of clinical trials;

- difficulties in identifying and treating patients suffering from our target indications, including those due to PBC and PSC being rare diseases and NASH currently requiring an invasive liver biopsy for diagnosis;

- the success of our clinical trials through all phases of clinical development, such as the success of our Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis;

- potential side effects of Ocaliva and our other product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;

- the required timeframe for us to receive and analyze data from our clinical trials;

- our ability to identify and develop additional product candidates;

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

- our ability to establish and maintain an effective sales and marketing infrastructure directly or through collaborations with third parties;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage or reimbursement for our products and the extent to which such coverage or reimbursement will be provided;
- our ability to adhere to clinical trial requirements directly or with third parties such as contract research organizations, or CROs;
- our dependency on third-party manufacturers to manufacture our products and key ingredients;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- the costs to us, and our ability and our third-party collaborators' ability to obtain, maintain and protect our intellectual property rights;
- costs related to and outcomes of potential intellectual property, securities and other litigation;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to build and improve our company's infrastructure, systems and controls;
- potential product liability claims; and
- our ability to obtain and maintain adequate insurance coverage.

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

We cannot be certain if Ocaliva will receive full approval for PBC in jurisdictions where it has received accelerated or conditional approval, or that Ocaliva will be approved for PBC in other jurisdictions. Furthermore, OCA may fail to become approved for any other indication and we may not be able to successfully receive regulatory approval for any other product candidate. Without regulatory approval, we will not be able to market and commercialize our product candidates.

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

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

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

We commenced our commercial launch of Ocaliva for PBC in certain European countries in 2017 after the European Commission granted conditional approval for Ocaliva for the treatment of PBC. The marketing authorization in the European Union is conditioned on the completion of the COBALT trial and a trial evaluating the safety and efficacy of Ocaliva in patients with moderate to severe hepatic impairment.

In May 2017, we received a marketing authorization with conditions for Ocaliva in PBC in Canada. We also plan to apply for marketing approval of Ocaliva for PBC in certain other markets across the world.

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

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

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

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

There can be no assurance that we will be able to receive marketing approval for OCA in PBC in jurisdictions where it is not yet approved or marketing approval for OCA in NASH or any other indication. We cannot predict whether our trials and studies as to NASH or any other indication or patient population will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or require us to conduct additional studies or trials. For example, while OCA received breakthrough therapy designation from the FDA in January 2015 for the treatment of NASH patients with liver fibrosis, we do not know if one pivotal clinical trial will be sufficient for marketing approval or if regulators will ultimately agree to a surrogate endpoint for accelerated approval of OCA for the treatment of NASH. While the interim analysis for the REGENERATE trial will be based on a histological endpoint as was the case in the Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health, our Phase 3 REGENERATE trial has different trial designs. For example, upon the finalization of a protocol amendment underway, the primary endpoint for the interim analysis for REGENERATE may be achieved based on one of: (i) the proportion of OCA-treated patients relative to placebo achieving at least one stage of liver fibrosis improvement with no worsening of NASH or (ii) the proportion of OCA-treated patients relative to placebo achieving NASH resolution with no worsening of liver fibrosis. Furthermore, we selected a definition for NASH resolution for the trial, which defines a responder as a patient achieving a histologic score of 0 for ballooning and 0 or 1 for inflammation. The REGENERATE trial will also remain blinded after the interim analysis and continue to follow patients until the occurrence of a pre-specified number of adverse liver-related clinical events, including progression to cirrhosis, to confirm clinical benefit on a post-marketing basis. While the statistical analysis planned for our REGENERATE trial is designed based on the data from the FLINT trial, the differences in the two trials may limit the utility of using FLINT as a basis for the design of the REGENERATE trial.

Furthermore, the Phase 2 dose ranging trial of OCA in 200 adult NASH patients in Japan conducted by our collaborator, Sumitomo Dainippon, did not meet its primary endpoint with statistical significance. In this trial, there was a dose dependent, although not statistically significant, increase in the percentage of OCA treated patients compared to placebo who achieved the primary endpoint ($p=0.053$). In addition, no difference was seen in fibrosis improvement in the OCA groups compared to placebo. The baseline characteristics between the patients in the Japanese Phase 2 trial conducted by Sumitomo Dainippon were distinct in a number of ways from those of the Western patients included in the Phase 2b FLINT trial conducted by NIDDK. For example, differences were observed among the patient population at baseline in relation to gender mix and metabolic factors like weight, diabetes status, dyslipidemia and hypertension. While our REGENERATE trial was designed based on the results of the FLINT trial and is anticipated to enroll a predominantly Western NASH patient population, the results of the FLINT trial may not be replicated in our REGENERATE trial. There is no assurance that Sumitomo Dainippon will initiate any registrational trials in NASH and the results of any additional trial conducted by Sumitomo Dainippon may not be an improvement as compared to those from the Phase 2 trial on Japanese NASH patients.

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

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

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

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

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

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

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

Our ongoing Phase 3 REGENERATE trial of OCA in non-cirrhotic NASH patients with liver fibrosis, incorporates an interim primary surrogate endpoint that may serve as the basis for a supplemental NDA filing for accelerated approval in the United States and approval in Europe. Accelerated approval in the United States and conditional approval in the European Union for OCA in NASH are subject to similar risks as discussed above in relation to OCA for PBC. The primary endpoint in the Phase 2b FLINT trial of OCA in NASH patients was based on liver biopsy and was defined as an improvement of two or more points in the NAFLD activity score (a system of scoring the histopathological features in the liver), or NAS, with no worsening of liver fibrosis. In contrast, upon the finalization of a protocol amendment underway, the primary endpoint for the interim analysis for REGENERATE may be achieved based on one of: (i) the proportion of OCA-treated patients relative to placebo achieving at least one stage of liver fibrosis improvement with no worsening of NASH or (ii) the proportion of OCA-treated patients relative to placebo achieving NASH resolution with no worsening of liver fibrosis. Furthermore, we selected a definition for NASH resolution for the trial, which defines a responder as a patient achieving a histologic score of 0 for ballooning and 0 or 1 for inflammation. Currently, other biopharmaceutical companies are enrolling or have initiated trials in certain subpopulations of NASH patients based on different endpoints from those in the FLINT and REGENERATE trials. Although the FDA acknowledged at recent workshops the possibility of granting accelerated approval for NASH therapies using surrogate endpoints, with potential examples including histological improvement, using the NAS or another scoring system, histological resolution of NASH, or improvements in fibrosis in pre-cirrhotic patients with NASH, the FDA did not provide any formal regulatory guidance on approvable endpoints and may not accept a surrogate endpoint for OCA for the treatment of NASH.

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

If we continue the development of OCA in PSC, we intend to seek marketing approval based on a surrogate endpoint. The FDA and EMA have not validated any surrogate endpoint as a basis for seeking approval in PSC and any surrogate endpoint we select may ultimately not be accepted by the regulatory agencies.

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

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

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

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

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

- the delay in receiving results from or the failure to achieve the necessary results in other clinical trials;

- inability to obtain approval from institutional review boards, or IRBs, to conduct a clinical trial at their respective sites;

- severe or unexpected drug-related adverse effects experienced by patients or any determination that a clinical trial presents unacceptable health risks;

- a breach of the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates, including Sumitomo Dainippon Pharma Co., Ltd., or Sumitomo Dainippon, or investigators leading clinical trials on our product candidates;

- inability to timely manufacture sufficient quantities of the product candidate required for a clinical trial;

- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our trial, the rarity of the disease or the characteristics of the population being studied, the risks of procedures that may be required as part of the trial, such as a liver biopsy, and competition from other clinical trial programs for the same indications as our product candidates; and

- inability to retain enrolled patients after a clinical trial is underway.

For example, our REGENERATE trial is a large and complex Phase 3 clinical trial in a disease without any approved therapies and involves serial liver biopsies. While we announced the completion of enrollment of the interim analysis cohort in May 2017, and continuously evaluate and implement a variety of options to complete enrollment as quickly as possible, there can be no assurance that we will be able to enroll a sufficient number of patients or complete the trial on a timely basis. As we engage in other large and complicated trials and trials in advanced disease populations, we may experience a number of complications that may negatively affect our plans or our development programs.

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

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

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

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

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

Although Ocaliva has received accelerated approval in the United States and conditional approval in the European Union, its full approval depends on the results of post-marketing clinical trials, including the Phase 4 COBALT trial. We cannot assure you that these trials will demonstrate a correlation of biochemical therapeutic response in patients taking Ocaliva with a significant reduction in adverse clinical events over time.

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

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

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

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

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

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

In the Phase 2 CONTROL trial, OCA treatment in the absence of statin therapy over the first four weeks resulted in an increase in LDL across all OCA treatment groups, while the placebo group was relatively unchanged. Treatment with atorvastatin beginning at week four and continuing through week 16 reversed OCA-related increases in LDL to below baseline levels in all OCA treatment groups. Dose-dependent pruritus was the most common adverse event in patients treated with OCA, occurring in 5% of patients on placebo, 5% of patients in the 5 mg OCA group, 10% of patients in the 10 mg OCA group and 55% of patients in the 25 mg OCA group. All events were mild to moderate and two patients discontinued treatment in the 25 mg OCA group due to pruritus. Over 95% of the patients completing the double-blind phase of CONTROL enrolled in the long-term safety extension phase of the trial.

During the ongoing long-term safety extension, or LTSE, phase of CONTROL, there has been one patient death. This patient was a 64 year-old male with a history of NASH associated liver cirrhosis, morbid obesity (BMI >40) and type 2 diabetes. At baseline, this patient had blood tests consistent with impaired liver function (e.g., low LDL and low platelets). The patient was randomized to placebo for the double-blind phase of the study. Early in the double-blind phase, the patient had serum biochemistry changes consistent with worsening hepatic impairment (e.g., albumin declined and bilirubin was increasing). Atorvastatin was started per protocol and then stopped early due to the patient's persistently low LDL levels. The patient later enrolled in the LTSE phase and began receiving 25 mg OCA treatment. Over the following four months, the patient's serum biochemistry remained consistent with ongoing hepatic impairment. Approximately five months after starting the LTSE phase, the patient developed severe protracted diarrhea which resulted in weight loss of 30 pounds over the ensuing one month period. Both an infectious cause and possible inflammatory bowel disease were suspected, and the patient subsequently was started on broad spectrum antibiotics and steroid therapy. Due to the diarrhea, the principal investigator stopped treatment with OCA and discontinued the patient from the study. Concurrently, the patient reported jaundice and was found to have significantly elevated serum bilirubin and ALP, while other liver enzymes remained relatively stable. Over the ensuing two-week period, various diagnostic tests and procedures were performed (e.g., magnetic resonance cholangiopancreatography [MRCP] to investigate possible gallstone bile duct obstruction) and the patient continued receiving a number of other medications, including the ongoing course of steroid therapy. During this time, the patient continued to deteriorate and was hospitalized with acute renal and liver failure, complicated by severe metabolic acidosis. The patient rapidly progressed to multi-organ system failure, sepsis and death.

The principal investigator determined that the events leading to the patient's death were unlikely related to OCA. Despite the numerous confounding factors in this case, given the contemporaneous administration of OCA during the patient's ongoing deterioration, we determined that it could not be ruled out that these events were possibly related to treatment. Subsequent to our determination, the independent data safety monitoring committee separately evaluated the case and determined that the events leading to the patient's death were unlikely related to OCA.

In our Phase 2 AESOP trial of OCA in PSC, pruritus was the most common adverse event, occurring in 46% of patients on placebo, 60% of patients in the 1.5 mg to 3 mg OCA group and 67% of patients in the 5 mg to 10 mg OCA group, with the severity increasing with dose. One (4%) patient in the 1.5 mg to 3 mg OCA group and three (12%) patients in the 5 mg to 10 mg OCA group discontinued OCA due to pruritus compared to none in the placebo group.

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

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

In addition, our drug candidates are being developed as potential treatments for severe, life threatening diseases and, as a result, our trials will necessarily be conducted in a patient population that will be more prone than the general population to exhibit certain disease states or adverse events. For example, as we expand our overall NASH development program, we intend to conduct trials in advanced patient populations, such as in our planned Phase 3 trial in NASH patients with cirrhosis. Ocaliva is used in patients suffering from various stages of PBC, which can be life threatening, and patients may suffer from other concomitant illnesses that may increase the likelihood of certain adverse events. It may be difficult to discern whether certain events or symptoms observed during our trials or in patients using commercial product were due to our drugs or drug candidates or some other factor, resulting in our company and our development programs being negatively affected even if such events or symptoms are ultimately determined to be unlikely related to our drugs and drug candidates. We further cannot assure you that additional or more severe adverse side effects with respect to OCA will not develop in future clinical trials or commercial use, which could delay or preclude regulatory approval of OCA or limit its commercial use.

If we or others later identify undesirable or unacceptable side effects caused by our products or product candidates:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

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

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

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

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

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same product for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. In addition, it is possible that orphan marketing exclusivity attaching to the marketing authorization will be reduced to six years if, at the end of the fifth year following the receipt of marketing authorization, the EMA and the Committee for Orphan Medicinal Products determine that the product does not satisfy the requisite criteria including demonstration of significant clinical benefit (having regard to requirements set out in the applicable EU regulations and guidance) where it is shown based on the available evidence that the product is sufficiently profitable to justify not to maintain the marketing exclusivity.

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

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

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

We do not intend to manufacture the pharmaceutical products that we plan to sell. We currently have agreements with a contract manufacturer for the production of the active pharmaceutical ingredients and the formulation of sufficient quantities of drug product for commercial sales and for our clinical trials and preclinical studies that we plan to conduct prior to and after seeking regulatory approval. If our contract manufacturer should cease to provide services to us for any reason, we likely would experience delays in advancing our clinical trials while we identify and qualify one or more replacement suppliers and we may be unable to obtain replacement supplies on terms that are favorable to us.

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

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

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

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

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

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

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

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

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

Risks Related to the Commercialization of Our Products

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance of Ocaliva or our product candidates, if approved. If there is not sufficient reimbursement for our products or they are not covered at all, it is less likely that they will be widely used.

Market acceptance and sales of any products or product candidates that we develop will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for Ocaliva or any other products and product candidates that we develop. Also, reimbursement policies could reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize Ocaliva or any other products or product candidates that we develop.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. Any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the United States. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. The ACA requires discounts under the Medicare drug benefit program and increased the rebates paid by pharmaceutical companies on drugs covered by Medicaid. The ACA also imposes an annual fee, which increases annually, on sales by branded pharmaceutical manufacturers. Following the November 2016 U.S. elections and the inauguration of President Trump, uncertainty exists about the future of the coverage expansion provided by the ACA; while Congressional efforts to repeal the ACA have not yet resulted in the passage of a bill, the President and congressional leaders continue to express interest in repealing these ACA provisions and replacing them with alternatives that may be less costly and provide state Medicaid programs and private health plans more flexibility. It is possible that these repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage and/or in individuals having insurance coverage with less generous benefits. The scope of potential future legislation to repeal and replace ACA provisions is highly uncertain in many respects, and it is possible that some of the ACA provisions that generally hurt the research-based pharmaceutical industry could also be repealed along with ACA coverage expansion provisions; however, at this time the coverage expansion provisions of the ACA appear most likely to be repealed and replaced.

In addition, third-party payors attempt to contain health care costs by demanding price discounts or rebates and limiting both the types and variety of drugs that they will cover and the amounts that they will pay for drugs. As a result, they may not cover or provide adequate payment for our products. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products or any other future products to such payors' satisfaction. Such studies might require us to commit a significant amount of management's time and our financial and other resources. Our products might not ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The market for a drug will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available, even if not approved for the indication for which the branded drug is approved. In addition, due to there being no uniform policy of coverage and reimbursement in the United States among commercial payors, coverage and reimbursement for pharmaceutical products may differ significantly from payor to payor.

We do not know if the price we have selected for Ocaliva will receive broad acceptance from third-party payors. The coverage determination process may be a time-consuming and costly process that requires us to provide scientific and clinical support for the use of Ocaliva in PBC to each payor separately, with no assurance that coverage will be obtained. If we are unable to obtain adequate coverage of Ocaliva from third-party payors, the adoption of Ocaliva by physicians and patients as a treatment for PBC may be limited. This in turn could affect our ability to successfully commercialize Ocaliva and adversely impact our profitability, results of operations, financial condition and future success.

Reimbursement in the European Union and many other territories must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. The timing to complete the negotiation process in each country is highly uncertain. While we have been able to achieve rapid reimbursement decisions in some countries, as in the case in the United Kingdom, we expect that it may still require a number of months before we receive a reimbursement decision in many other countries. Even after a price is negotiated, countries frequently request or require adjustments to the price and other concessions over time or require approvals regionally. Reimbursement agencies in Europe are often more conservative than those in the United States and the reimbursement process is often slower since reimbursement decisions are made on a country-by-country basis. Prices for drugs in Europe generally decrease over time.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of OCA and any other products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. Pricing pressures recently experienced by the pharmaceutical industry may be further exacerbated by legislative and policy changes under consideration by the Trump administration.

Ocaliva and other product candidates, if approved, may not achieve broad market acceptance among physicians, patients and healthcare payors, and as a result our revenues generated from their sales may be limited.

The commercial success of Ocaliva or our other products or product candidates that we develop, if approved, will depend upon their acceptance among the medical community, including physicians, healthcare payors and patients. In order for Ocaliva to be commercially successful in PBC, we will need to demonstrate its utility as a treatment for patients who have an inadequate response to or who are unable to tolerate ursodiol, referred to as second line treatment, and show that it is more effective than any other alternatives that may be developed as a second line treatment for PBC, particularly given the much higher price that we charge for Ocaliva compared to the price of generically available ursodiol. Ocaliva also must be shown to be a safe and tolerable treatment in a commercial use setting as it is intended to be a lifetime therapy for patients eligible for treatment. In NASH and PSC, since there are currently no approved therapies, we do not know the degree to which OCA will be accepted as a therapy, even if approved.

The degree of market acceptance of our product candidates will depend on a number of factors, including:

- limitations or warnings contained in our product candidates' FDA or EMA-approved labeling;
- changes in the standard of care or availability of alternative therapies at similar or lower costs for the targeted indications for any of our product candidates, such as ursodiol for the treatment of PBC;
- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness;
- availability of alternative therapies at similar or lower cost, including generics and over-the-counter products;
- the extent to which our product candidates are approved for inclusion on formularies of hospitals and managed care organizations;
- whether our product candidates are designated under physician treatment guidelines for the treatment of the indications for which we have received regulatory approval;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our product candidates; and
- potential product liability claims.

In addition, the potential market opportunity for our products and product candidates is difficult to precisely estimate. While ursodiol is the established standard of care for PBC, a majority of patients while on therapy remain at ALP levels above the upper limit of normal, or ULN. According to our analysis of industry data in PBC, approximately 65% of patients treated with ursodiol experience elevated ALP levels, with approximately 35% of patients experiencing ALP levels greater than 1.67 times ULN. In addition, a small minority of PBC patients (estimated at approximately 3% of patients) are intolerant to ursodiol therapy. Our estimates of the potential market opportunity for Ocaliva for the treatment of PBC include a number of key assumptions related to prevalence rates, patients' access to healthcare, diagnosis rates and patients' response to or tolerance of OCA, which are based on available literature and epidemiology research in PBC, our industry knowledge gained through market research and other methods, industry publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of these assumptions prove to be inaccurate, then the actual market for Ocaliva in PBC could be smaller than our estimates of our potential market opportunity. If the actual market opportunity for Ocaliva or our product candidates is smaller than we expect, our product revenue may be limited.

If our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community and healthcare payors, sufficient revenue may not be generated from these products and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

We have limited sales, marketing or distribution experience and we will have to invest in significant additional resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.

We have limited sales, marketing or distribution experience as a commercial organization. The commercial launch of Ocaliva for PBC represents our first product launch. We also plan to commercialize Ocaliva for PBC in certain other countries outside of the United States and Europe ourselves with a targeted sales force if we receive marketing approval. We may utilize the services of third-party collaborators in certain other jurisdictions. We have not yet decided on our commercialization strategy for OCA in other indications and for our other product candidates. To develop internal sales, distribution and marketing capabilities, we have invested and expect to continue to invest significant additional amounts of financial and management resources.

Recruiting and training a commercial organization is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel.

For product candidates where we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including:

- we or our third-party sales collaborators may not be able to attract and build, or retain an effective marketing or sales force;

- the cost of securing or establishing a marketing or sales force may exceed the revenues generated by any products; and

- our direct sales and marketing efforts may not be successful.

We have a collaboration with Sumitomo Dainippon for the development and commercialization of OCA in Japan, China, South Korea and potentially other Asian countries, if approved, and may elect to seek additional strategic collaborators for our product candidates. We may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, commonly referred to as “fraud and abuse” laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions such as Europe have similar laws and are enacting more stringent regulations. These laws include false claims and anti-kickback statutes. If we market our products and our products are paid for by governmental programs, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service covered by Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

We will incur significant liability if it is determined that we are promoting any "off-label" use of Ocaliva.

Physicians are permitted to prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies are not permitted to promote drugs for off-label uses. Accordingly, we may not promote Ocaliva in the United States for use in any indications other than for the treatment of patients with PBC in combination with ursodiol in adults with an inadequate response to ursodiol or as monotherapy in adults unable to tolerate ursodiol. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses will be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various governmental authorities in the United States and abroad.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We intend to continue engaging in medical education activities and communicate with healthcare providers in compliance with all applicable laws, regulatory guidance and industry best practices.

While we have implemented a corporate compliance program based on what we believe are the current best practices, we cannot provide any assurance that governmental authorities will find that our business practices comply with current or future administrative or judicial interpretations of potentially applicable laws and regulations. If we fail to comply with any of these laws and regulations, we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of Ocaliva or other products from the market, significant fines, disqualification or debarment from participation in federally-funded healthcare programs or other sanctions or litigation, any of which events may have a significant adverse impact on our business.

If any of our current strategic collaborators fails to perform its obligations or terminates its agreement with us, the development and commercialization of the products or product candidates under such agreement could be delayed or terminated and our business could be substantially harmed.

We currently have strategic collaborations in place relating to certain of our product candidates. We entered into an exclusive license agreement with Sumitomo Dainippon regarding the development and commercialization of Ocaliva for PBC and OCA for NASH in Japan, China and South Korea and provided Sumitomo Dainippon with an option to extend its exclusive license to different indications as well as certain other Asian countries. These strategic collaborations may not be scientifically or commercially successful due to a number of important factors, including the following:

- Sumitomo Dainippon has significant discretion in determining the efforts and resources that each will apply to its strategic collaboration with us. The timing and amount of any cash payments, milestones and royalties that we may receive under such agreement will depend on, among other things, the efforts, allocation of resources and successful development and commercialization of our product candidates by Sumitomo Dainippon under the agreement;

- Our agreement with Sumitomo Dainippon restricts it from developing or commercializing any FXR agonist to treat PBC or NASH during the term of the agreement other than pursuant to the Sumitomo Dainippon agreement. Subject to these restrictions, it is possible that Sumitomo Dainippon may develop and commercialize, either alone or with others, or be acquired by a company that has, products that are similar to or competitive with the product candidates that it licenses from us;

- Sumitomo Dainippon may change the focus of its development and commercialization efforts or pursue higher-priority programs;

- Sumitomo Dainippon may, under specified circumstances, terminate its strategic collaborations with us on short notice and for circumstances outside of our control, which could make it difficult for us to attract new strategic collaborators or adversely affect how we are perceived in the scientific and financial communities;

- Sumitomo Dainippon has, under certain circumstances, the right to maintain or defend our intellectual property rights licensed to them in their territories, and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our strategic collaborator does not, our ability to do so may be compromised by our strategic collaborator's acts or omissions;

- Sumitomo Dainippon may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability; and

- Sumitomo Dainippon may not comply with all applicable regulatory requirements, or fail to report safety data in accordance with all applicable regulatory requirements.

If Sumitomo Dainippon fails to develop or effectively commercialize OCA, we may not be able to replace it with another collaborator. For example, there is no assurance that Sumitomo Dainippon will initiate any registrational trials in NASH and the results of any additional trial conducted by Sumitomo Dainippon may not be an improvement as compared to those from the Phase 2 trial on Japanese NASH patients. We may also be unable to obtain, on terms acceptable to us, a license from such strategic collaborator to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize a product candidate. Any of these events could have a material adverse effect on our business, results of operations and our ability to achieve future profitability, and could cause our stock price to decline.

We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, expanding manufacturing capabilities and marketing approved products are expensive, we have entered into, and may seek to enter into, collaborations with companies that have more experience and resources than we have. For example, we have entered into a collaboration with Sumitomo Dainippon for OCA. We may establish additional collaborations for development and commercialization of OCA in territories outside of those licensed by Sumitomo Dainippon and for other product candidates and research programs, including INT-767 and INT-777. Additionally, if any of our product candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties with respect to our unlicensed territories. If we are unable to maintain our existing arrangements or enter into any new such arrangements on acceptable terms, if at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our product candidates.

When we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. For example, Sumitomo Dainippon has the exclusive rights to OCA in Japan, China and South Korea and a right of first refusal to license OCA in several other Asian countries. Our collaboration partner may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into, including our collaboration with Sumitomo Dainippon, may be unsuccessful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a product candidate or research program under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators for our product candidates, we would face increased costs, we may be forced to limit the number of our product candidates we can commercially develop or the territories in which we commercialize them and we might fail to commercialize products or programs for which a suitable collaborator cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition will be materially and adversely affected.

If we fail to develop OCA for additional indications, our commercial opportunity will be limited.

To date, we have focused the majority of our development efforts on the development of OCA. Among our other product candidates, only INT-767 is currently in clinical development. One of our strategies is to pursue clinical development of OCA in NASH and other progressive non-viral liver diseases, to the extent that we have sufficient funding.

PBC is an orphan disease. Since Ocaliva is indicated for use in PBC in combination with ursodiol in adults with an inadequate response to ursodiol or as monotherapy in adults unable to tolerate ursodiol, the market size is expected to be limited. Furthermore, because a significant proportion of PBC patients do not exhibit any symptoms at the time of diagnosis, PBC may be left undiagnosed for a significant period of time. Due to these factors, our ability to grow revenues will be dependent on our ability to successfully develop and commercialize OCA for the treatment of additional indications. In particular, we believe that our future success will depend in large part on the results of our development of OCA for the treatment of NASH. Although NASH is believed to be one of the most prevalent chronic liver diseases worldwide, NASH may be left undiagnosed for a long time and a definitive diagnosis of NASH is currently based on a histological assessment of a liver biopsy, which impacts the ability to easily identify patients. Furthermore, even if we are successful in developing and obtaining marketing approval of OCA for the treatment of NASH, we may not be able to commercialize OCA successfully.

The completion of development, securing of approval and commercialization of OCA for additional indications will require substantial additional funding and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be able to successfully advance any of these indications through the development process. Even if we receive FDA or EMA approval to market OCA for the treatment of any of these additional indications, we cannot assure you that any such additional indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize OCA for these additional indications, our commercial opportunity will be limited and our business prospects will suffer.

Risks Related to Our Business and Strategy

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in the United States, Europe and other jurisdictions, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA or EMA approval or discovering, developing and commercializing drugs for the diseases that we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Some of the pharmaceutical and biotechnology companies we expect to compete with include Allergan Plc, AstraZeneca plc, Acorda Therapeutics, Inc., Boehringer Ingelheim GmbH, Bristol-Myers Squibb Company, Conatus Pharmaceuticals Inc., Cymabay Therapeutics, Inc., Dr. Falk Pharma GmbH, Durect Corporation, Enanta Pharmaceuticals, Inc., ENYO Pharma SAS, Galectin Therapeutics Inc., Galmed Medical Research Ltd., Genfit SA, Gilead Sciences, Inc., GlaxoSmithKline, Immuron Ltd., Islet Sciences, Inc., Madrigal Pharmaceuticals, Inc., Metacrine, Inc., MiNA Therapeutics, NGM Biopharmaceuticals, Novartis International AG, Novo Nordisk A/S, Shire plc, Viking Therapeutics, Inc. and Zydus Pharmaceuticals Inc. Bezafibrate, a fibrate that has not been approved for commercialization by the FDA and is only available outside of the United States, has been studied in multiple clinical trials for the treatment of liver diseases including PBC and NASH. Genfit SA has an ongoing Phase 3 clinical trial of GFT505, a dual PPAR alpha/delta agonist, in NASH. Genfit is also studying GFT505 for the treatment of PBC. Gilead Sciences, Inc. is conducting multiple Phase 3 clinical trials in NASH patients of various disease severity with selonsertib, an inhibitor of the apoptosis signal-regulating kinase 1. Gilead Sciences, Inc. is also exploring additional studies in NASH for GS-0976, a small molecule allosteric inhibitor that acts at the protein-protein homodimer interface of acetyl-CoA carboxylases acquired from Nimbus Therapeutics, LLC, and an FXR agonist known as GS-9674. Gilead Sciences, Inc. is also studying a number of compounds in other liver diseases including PBC and PSC. Allergan Plc has an ongoing Phase 3 clinical trial of cenicriviroc, an immunomodulator that blocks C-C chemokine receptor type 2 and type 5, for the treatment of NASH. A number of other companies have trials in PBC, NASH and other liver diseases we are targeting.

In addition, many universities and private and public research institutes may become active in our target disease areas. The results from our POISE and FLINT trials and the approval of Ocaliva for PBC have brought more attention to our targeted indications and bile acid chemistry. As a result, we believe that additional companies and organizations may seek to compete with us in the future. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than OCA or any other product candidates that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive.

Off-label uses of other potential treatments may limit the commercial potential of our product candidates, especially given the pricing of Ocaliva and the anticipated pricing for our product candidates. For example, while fibrates are not approved for use in PBC, off-label use of fibrate drugs has been reported, though many fibrates are specifically contraindicated for use in PBC due to potential concerns over acute and long-term safety in this patient population. In NASH, a number of treatments, including vitamin E (an antioxidant), insulin sensitizers (such as metformin), antihyperlipidemic agents (such as gemfibrozil), pentoxifylline and ursodiol, are used off-label. Although none of these treatments have been clearly shown in clinical trials to alter the course of the disease, in a previous study conducted by the NASH Clinical Research Network, similar improvements to those observed with OCA in the FLINT trial in certain histological measures of NASH were reported with vitamin E and pioglitazone. Various other treatments, both approved and unapproved, have been used in the other indications we are targeting.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our and our strategic collaborators’ clinical trials and preclinical studies;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety and reliability of Ocaliva and our other product candidates;
- the speed at which we develop our product candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to maintain a good relationship with regulatory authorities;

- the timing and scope of regulatory approvals, if any;
- our ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products;
- adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect intellectual property rights related to our products;
- our ability to manufacture and sell commercial quantities of any approved products to the market; and
- acceptance of our product candidates by physicians and other health care providers.

If our competitors market products that are more effective, safer or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We depend on third-party contractors for a substantial portion of our operations and may not be able to control their work as effectively as if we performed these functions ourselves.

We outsource and plan to continue to outsource substantial portions of our operations to third-party service providers, including the conduct of preclinical studies and clinical trials, collection and analysis of data and manufacturing. Although we are currently commercializing Ocaliva using our internal commercial organization, we will likely use the services of third-party vendors in relation to our future commercialization activities, including product sales, marketing and distribution. Our agreements with third-party service providers are on a study-by-study and/or project-by-project basis. Typically, we may terminate the agreements with notice and are responsible for the supplier's previously incurred costs. In addition, a number of third-party service providers that we retain will be subject to the FDA's and EMA's regulatory requirements and similar standards outside of the United States and Europe and we do not have control over compliance with these regulations by these providers. Consequently, if these providers do not adhere to applicable governing practices and standards, the development and commercialization of Ocaliva and our other product candidates could be delayed or stopped, which could severely harm our business and financial condition.

Because we have relied on third parties, our internal capacity to perform these functions is limited to management oversight. Outsourcing these functions involves the risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In the past, we experienced difficulties with a third-party contract manufacturer for OCA, including delays in receiving adequate clinical trial supplies as requested within the requested time periods. We subsequently replaced this manufacturer with other third-party contract manufacturers for OCA. It is possible that we could experience similar difficulties in the future. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. There are a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. Despite our recent growth, we currently have a small number of employees, which limits the internal resources we have available to identify and monitor third-party service providers. To the extent we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. We may further be subject to the imposition of civil or criminal penalties if their conduct of clinical trials violates applicable law.

Our third-party service providers generally are not prohibited from providing their services to other biopharmaceutical companies, including companies that currently or may in the future compete with us. For example, certain of our third-party service providers and consultants may be able to develop intellectual property to which we are not entitled under our agreements which may eventually be used to develop products that compete with our products. Although we generally have confidentiality and non-disclosure agreements in place with our third-party service providers and consultants, such third parties may be able to provide services to other companies without violating the terms of our agreements. In addition, although we may seek to enter into non-compete arrangements with our key third-party service providers, such arrangements are difficult to negotiate and we may be unable to successfully enter into such arrangements.

A variety of risks associated with our international business operations and our planned international business relationships could materially adversely affect our business.

We have a wholly-owned subsidiary in the United Kingdom which serves as our headquarters for our international operations. We have also formed a number of other wholly-owned subsidiaries in Europe and Canada in preparation for the anticipated commercial launch of Ocaliva in PBC in those jurisdictions. Although we are currently commercializing Ocaliva using our internal commercial organization, we will likely use the services of third-party vendors in relation to our future commercialization activities, including product sales, marketing and distribution. In addition, we have entered into collaborations with Sumitomo Dainippon for the development of OCA, and we may enter into agreements with other third parties for the development and commercialization of OCA or our other product candidates in international markets. Our international operations and business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for drug approvals internationally;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in countries outside of the United States;
- the potential for so-called “parallel importing,” which is what occurs when a local seller, e.g., a pharmacy, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- taxes in other countries;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

For example, we do not know the extent of the impact that the Brexit will have on our business. As a result of the Brexit, it is possible that Scotland and Northern Ireland may each conduct a referendum to decide whether to leave the United Kingdom. Furthermore, other European countries may seek to conduct referenda with respect to continuing membership with the European Union. We do not know to what extent these changes will impact our business. Our ability to conduct our international business out of the United Kingdom may be materially and adversely affected.

Changes in our effective income tax rate could adversely affect our results of operations.

We are subject to income taxes in the United States and various foreign jurisdictions. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, the accounting for stock options and other stock-based compensation, changes in accounting standards, future levels of research and development spending, changes in the mix and level of pre-tax earnings by taxing jurisdiction, the outcome of examinations by the U.S. Internal Revenue Service and regulators of other jurisdictions, the accuracy of our estimates for unrecognized tax benefits, the realization of deferred tax assets, or by changes to our ownership or capital structure. The impact on our effective income tax rate resulting from the above-mentioned factors and others may be significant and could adversely affect our results of operations.

We have been significantly expanding our operations and the size of our company and will need to continue our expansion to support our NASH program. We may experience difficulties in managing our significant growth.

From December 31, 2014 to December 31, 2016, our employee base has grown from 136 to 456 employees. As we advance our programs for OCA in NASH and other potential indications and our other product candidates, seek regulatory approval in the United States and elsewhere, increase the number of ongoing product development programs and advance our product candidates through preclinical studies and clinical trials, we will need to increase our product development, scientific and administrative headcount to manage these programs. We will also need to grow our commercial capabilities, which will require us to hire additional personnel for the launch and ongoing marketing and sale of Ocaliva in PBC and any product candidate for which we obtain marketing approval. In addition, in order to continue to meet our obligations as a public company and to support the anticipated longer-term growth in the other functions at our company, we will need to increase our general and administrative capabilities. We are also expanding our operations geographically and formed a number of wholly-owned subsidiaries outside of the United States. In addition to our U.S. offices, we also have an office in London, United Kingdom which serves as our headquarters for our operations in Europe and international markets, and regional offices in a number of these countries. In the longer term, we may further expand our geographical footprint. Our management, personnel and systems currently in place may not be adequate to support this future growth. Furthermore, we may face a number of complexities, such as being subject to national collective bargaining agreements for employees, in some of the countries in which we operate.

Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the expertise and experience we will require in the United States, Europe and in other jurisdictions;

- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites across the world, and advance our other development efforts;

- develop and expand our marketing and sales infrastructure; and

- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified personnel and consultants across our organization due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercial objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of Mark Pruzanski, our co-founder and president and chief executive officer, and our other key employees and consultants. If we lose one or more of our executive officers, or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time. Replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants.

We have scientific and clinical advisors and consultants, such as our co-founder Professor Roberto Pellicciari, who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Failure to establish and maintain adequate finance infrastructure and accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, and the related rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

Our compliance with Section 404 of the Sarbanes-Oxley Act has required and will continue to require that we incur substantial accounting expense and expend significant management efforts. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner so as to be able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act each year. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner each year, we could be subject to sanctions or investigations by the Securities and Exchange Commission, the NASDAQ Stock Market or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations in the United States and abroad intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Misconduct and misappropriation of confidential information by our employees or third parties may also include improper trading in our securities, which may harm our reputation and result in enforcement actions against us. We have adopted a global code of business conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for our products and product candidates and may have to limit their use.

The use of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval, such as Ocaliva in PBC, expose us to the risk of product liability claims. Product liability claims may be brought against us or our collaborators by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for our product candidates and loss of revenues;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates or the withdrawal of our products from the market.

We have obtained limited product liability insurance coverage in the United States for the use of OCA in our U.S. clinical trials and commercial sales and in selected other jurisdictions where we are conducting clinical trials. Our product liability insurance coverage in the United States is currently limited to an aggregate of $10 million. We have clinical trial and commercial product liability insurance coverage outside of the United States in amounts that vary by country. As such, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash resources and adversely affect our business.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. Furthermore, the increased volatility of our stock price may result in us being required to pay substantially higher premiums for our directors' and officers' insurance than those to which we are currently subject, and may even lead a large number of underwriters to be unwilling to cover us.

If we engage in an in-license transaction, acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time, we have considered, and we will continue to consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include in-licensing or acquiring products, technologies or business or entering into a business combination with another company. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources to integrate new products, technologies or businesses;
- assume substantial actual or contingent liabilities;
- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash and/or shares of the other company on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider in-license transactions, acquisitions, reorganizations and business combinations in the future, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

Our business and operations would suffer in the event of system failures or data breaches.

Despite the implementation of security measures and policies, our internal information technology systems, as well as those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Information security risks have significantly increased in recent years in part due to the proliferation of new technologies and the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign state actors. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities.

Although to date we have not experienced any material losses relating to cyber-attacks or other information security breaches, there can be no assurance that we will not suffer such losses in the future. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs, damage to our reputation and/or monetary damages. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Our information security systems are subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, the Health Insurance Portability and Accountability Act, or HIPAA, and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information. In addition to HIPAA, numerous other federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information.

Various foreign countries where we may process personal information also have, or are developing, laws governing the collection, use, disclosure and storage of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues that may affect our business. In July 2016, U.S. and European Commission officials adopted a new framework called the EU-U.S. Privacy Shield to govern cross-border flows of personal data. We adopted the EU-U.S. Privacy Shield and certified to its requirements in October 2016. In May 2018, the General Data Protection Regulation ("GDPR") will supersede current EU data protection legislation, impose more stringent EU data protection requirements, and provide for greater penalties for noncompliance. While we are actively employing the EU-U.S. Privacy Shield as a means to legitimize the transfer of personal information from the EU and Switzerland to the United States, and are engaging in activities to comply with the GDPR requirements, we may be unsuccessful in these efforts.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our products and product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future products and product candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products and product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently own or may own in the future, or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in infringement, interference, derivation, opposition or invalidity proceedings before U.S. or non-U.S. patent offices. Our patents may also be challenged under other proceedings, such as *inter partes review* and post-grant review proceedings introduced by provisions of the America Invents Act.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our products and product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

As of June 30, 2017, we were the owner of record of over 110 issued or granted U.S. and non-U.S. patents relating to OCA with claims directed to pharmaceutical compounds, pharmaceutical compositions, methods of making these compounds, and methods of using these compounds in various indications. We were also the owner at that date of record of over 80 pending U.S. and non-U.S. patent applications relating to OCA in these areas.

In addition, as of June 30, 2017, we were the owner of record of approximately 200 issued or granted U.S. and non-U.S. patents relating to our product candidates other than OCA, with claims directed to pharmaceutical compounds, pharmaceutical compositions, methods of making these compounds and methods of using these compounds in various indications. We were also the owner of record of over 70 pending U.S. and non-U.S. patent applications relating to such other product candidates in these areas.

Patents covering the composition of matter of OCA expire in 2022 at the soonest and 2033 at the latest if the appropriate maintenance renewal, annuity, or other government fees are paid. We expect that the other patents in the OCA portfolio, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, would expire from 2022 to 2033. We expect the issued INT-767 composition of matter patent in the United States, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2029. We expect the other patents in the INT-767 portfolio, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2027 to 2029. We expect the issued INT-777 composition of matter patent in the United States, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire in 2030. We expect the other patents in the INT-777 portfolio, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, to expire from 2028 to 2030.

We have received assignments of rights to the INT-767 patent portfolio from all inventors, with the exception of one inventor. That inventor is contractually obligated to provide an assignment to us. Thus, we believe that we are the owner of the INT-767 patent portfolio by virtue of this contractual obligation and the patent assignments we have received. By virtue of the patent assignments we have received and other contractual obligations owed to us, we believe we are the owner of the INT-777 patent portfolio. Without patent protection on the composition of matter of our products and product candidates, our ability to stop others from using or selling our products and product candidates may be limited.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our products and product candidates or methods involving these candidates in the parent patent application. We plan to pursue divisional patent applications or continuation patent applications in the United States and other countries to obtain claim coverage for inventions which were disclosed but not claimed in the parent patent application.

If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the United States by extending the patent terms and obtaining data exclusivity for our products and product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our products and product candidates, U.S. patents may be eligible for limited extension of patent term under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits an extension of patent term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, an extension may not be granted because of, for example, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents or failure to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than what is requested. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Our primary composition of matter patent for OCA expires in 2022. In light of the U.S. marketing approval of OCA in PBC in May 2016, we have applied for an extension to the patent term for this patent in the United States through 2027. We expect to take similar actions in other jurisdictions and countries where similar regulations exist. In the event that we are unable to obtain any patent term extensions, the issued composition of matter patents for OCA are expected to expire in 2022 at the soonest and 2033 at the latest, assuming they withstand any challenge. We expect that the other patents for the OCA portfolio, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, would expire from 2022 to 2033.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court or engage in other adversarial proceedings to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court or adjudicating body to rule that such patents are invalid, not infringed, or should not be enforced against that third party. These lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court or adjudicating body will decide that such patents are not valid or not infringed, and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court or adjudicating body will refuse to stop the other party on the ground that such other party’s activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has modified some tests used by the U.S. Patent and Trademark Office, or USPTO, in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product and product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our products, or manufacture or use of our product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party’s patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products and product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party’s patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt commercialization of the relevant product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party’s patents. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we fail to obtain a license, develop or obtain non-infringing technology or defend an infringement action successfully, or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our products and product candidates to market and be precluded from manufacturing or selling our products and product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be unpublished or otherwise maintained in secrecy until the patents are issued;

- patent applications in the United States are typically not published until 18 months after the priority date; and

- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and such patent applications may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ a third-party service provider and rely on this service provider to pay these fees due to the USPTO and non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, in September 2016, the Department of Health and Human Services adopted new regulations mandating sponsors to publicly post certain data from clinical trials of products subject to FDA regulation. Although the implementation of the regulations may be delayed, this and other transparency initiatives may result in making publicly available information we may consider to be trade secrets or proprietary information. Moreover, the EMA has already adopted a policy of general transparency both in relation to requests under EU freedom of information legislation for access to pre-clinical and clinical research data once marketing authorizations are granted and through proactive disclosure of clinical data on its website. This policy coupled with imminent requirements for public disclosure of clinical research data under a new EU Clinical Trial Regulation, means that public disclosure will ordinarily be made of substantial research data that previously would have been considered commercially confidential. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We have not yet registered all of our trademarks and failure to secure those registrations could adversely affect our business.

We have applied for and obtained a number of trademarks and service marks to further protect the proprietary position of our products. As of June 30, 2017, we have over 490 trademark and service mark registrations and over 380 pending trademark and service mark applications in the United States and abroad. Our trademark applications may not be allowed for registration or our registered trademarks may not be maintained or enforced. During prosecution of applications for trademark registration, we may receive rejections or refusals. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many other jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings have been filed and may in the future be filed against certain of our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Trademark protection varies in accordance with local law, and continues in some countries as long as the trademark is used and in other countries as long as the trademark is registered. Trademark registrations generally are for fixed but renewable terms. We cannot provide any assurances that any trademarks or service marks will be sufficient to prevent competitors from adopting similar names. The adoption of similar names by competitors could impede our ability to build brand identity and lead to customer confusion, which could adversely affect our sales or profitability.

We have received approval from both the FDA and EMA for Ocaliva®, the proprietary name for OCA, as well as the associated logo. The Ocaliva trademarks have registered in jurisdictions, including the United States, member states of the Community Trademark, Australia, Great Britain, New Zealand, Norway, Switzerland, Taiwan and certain other countries.

Risks Related to Our Indebtedness

Servicing our debt will require significant amounts of cash, and we may not have sufficient cash flow from our business to pay our debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance the $460.0 million aggregate principal amount of 3.25% convertible senior notes due 2023 we issued in July 2016, or convertible notes or any indebtedness we or our subsidiaries may incur in the future depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt, including the convertible notes. If we are unable to generate cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be unfavorable to us or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at the time we seek to refinance such indebtedness. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may incur substantially more debt or take other actions which would affect our ability to pay the principal of and interest on our debt.

We and our subsidiaries may be able to incur substantial additional debt in the future, some of which may be secured debt. We and our subsidiaries will not be restricted under the terms of the indenture governing the convertible notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing the convertible notes that could have the effect of diminishing our ability to service our debt when due.

The conditional conversion feature of the convertible notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the convertible notes is triggered, holders will be entitled to convert their convertible notes at any time during specified periods at their option. If one or more holders elect to convert their convertible notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their convertible notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the convertible notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

The accounting method for convertible debt securities that may be settled in cash, such as the convertible notes, is the subject of recent changes that could have a material effect on our reported financial results.

Under Accounting Standards Codification 470-20, Debt with Conversion and Other Options, which we refer to as ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the convertible notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer’s economic interest cost. The effect of ASC 470-20 on the accounting for the convertible notes is that the equity component is required to be included in the additional paid-in capital section of stockholders’ equity on our consolidated balance sheet, and the value of the equity component would be treated as original issue discount for purposes of accounting for the debt component of the convertible notes. As a result, we will be required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the convertible notes to their face amount over the term of the convertible notes. We will report lower net income in our financial results because ASC 470-20 will require interest to include both the current period’s amortization of the debt discount and the instrument’s coupon interest, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the convertible notes.

In addition, under certain circumstances, convertible debt instruments (such as the convertible notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the convertible notes will not be included in the calculation of diluted earnings per share except to the extent that the conversion value of the notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the convertible notes, then our diluted earnings per share would be adversely affected.

Provisions in the indenture governing the convertible notes may deter or prevent a business combination that may be favorable to you.

If a fundamental change occurs prior to the maturity date of the convertible notes, holders of the convertible notes will have the right, at their option, to require us to repurchase all or a portion of their convertible notes. In addition, if a make-whole fundamental change occurs prior to the maturity date of the convertible notes, we will in some cases be required to increase the conversion rate for a holder that elects to convert its convertible notes in connection with such make-whole fundamental change. Furthermore, the indenture governing the convertible notes prohibits us from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the convertible notes and the indenture. These and other provisions in the indenture could deter or prevent a third party from acquiring us even when the acquisition may be favorable to you.

Risks Related to Ownership of Our Common Stock

An active trading market in our common stock may not be maintained.

The trading market in our common stock has been extremely volatile. The quotation of our common stock on The NASDAQ Global Select Market does not assure that a meaningful, consistent and liquid trading market will exist. We cannot predict whether an active market for our common stock will be maintained in the future. An absence of an active trading market could adversely affect our stockholders’ ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. As of June 30, 2017, approximately 30.1% of our outstanding shares of common stock was held by our officers, directors, beneficial owners of 5% or more of our securities (other than FMR LLC, Carmignac Gestion, Capital World Investors, Ameriprise Financial, Inc. and their respective affiliates) and their respective affiliates, which adversely affects the liquidity of the trading market for our common stock, in as much as federal securities laws restrict sales of our shares by these stockholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price.

We were previously subject to securities class action litigation and may be subject to similar or other litigation in the future, which may divert management's attention.

We have previously been subject to securities class action lawsuits. In February 2014, two purported securities class actions were filed against us and certain of our officers, which were eventually consolidated. In May 2016, the defendants reached an agreement with the lead plaintiff to seek Court approval of a proposed resolution and the settlement was ultimately granted final approval by the Court in September 2016. While the final judgment and order of the Court included a dismissal of the action with prejudice against all defendants and the defendants did not admit any liability as part of the settlement, the total payment aggregated to $55.0 million, of which $10.0 million was paid by our insurers. There may be additional suits or proceedings brought in the future. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities, and we cannot predict how long it may take to resolve these matters. In addition, we may incur substantial legal fees and costs in connection with litigation. Although we may receive insurance coverage for certain adversarial proceedings, coverage could be denied or prove to be insufficient. It is possible that we could, in the future, incur judgment or enter into settlement of claims for monetary damages. A decision adverse to our interests could result in the payment of substantial damages and could have a material adverse effect on our business, results of operations and financial condition.

Our stock price has been and may in the future be volatile, which could cause holders of our common stock and the Convertible Notes to incur substantial losses.

The trading price of our common stock has been, and is likely to continue to be, highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Since our initial public offering which occurred in October 2012, the price of our common stock on The NASDAQ Global Select Market has ranged from $17.96 per share to $497.00 per share. In addition to the other factors discussed in this "Risk Factors" section, these factors include:

- failure to successfully commercialize Ocaliva for PBC in jurisdictions where we have received marketing authorization or our inability to receive marketing approval for Ocaliva in other jurisdictions;
- adverse results or delays in our clinical trials;
- inability to obtain additional funding;
- any delay in filing an IND, NDA, MAA or comparable submission for any of our products and product candidates and any adverse development or perceived adverse development with respect to the regulatory review of such submission;
- failure to successfully develop and commercialize OCA for indications other than PBC and any of our other product candidates;
- inability to obtain adequate product supply for OCA and our future product candidates or the inability to do so at acceptable prices;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- changes in laws or regulations applicable to our products or future products;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;
- competition from existing products or new products that may emerge;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;

- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- announcement or expectation of additional financing efforts;

- significant lawsuits, including patent, stockholder or product liability litigation, involving us;

- sales of our common stock by us, our insiders or our other stockholders;

- failure to adopt appropriate information security systems, including any systems that may be required to support our growing and changing business requirements;

- market conditions for biopharmaceutical stocks in general; and

- general economic, industry and market conditions.

Furthermore, the stock markets in general and the market for biotechnology companies in particular have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations may negatively impact the market price of shares of our common stock, regardless of our actual operating performance. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We have been in the past, and may be in the future, the target of this type of litigation, which could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. As a result of this volatility, our stockholders could incur substantial losses.

We have a significant stockholder, which will limit your ability to influence corporate matters, may give rise to conflicts of interest and could result in future substantial sales of shares of our common stock into the market.

Genextra S.p.A., together with its affiliates, whom we refer to collectively as Genextra, is our largest stockholder. As of June 30, 2017, Genextra owned 6,454,953 shares of our common stock. The shares of common stock owned by Genextra represented approximately 25.7% of our outstanding common stock as of June 30, 2017. Accordingly, Genextra exerts and will continue to exert significant influence over us and any action requiring the approval of the holders of our common stock, including the election of directors and amendments to our organizational documents, such as increases in our authorized shares of common stock and approval of significant corporate transactions. This concentration of voting power makes it less likely that any other holder of common stock or directors of our business will be able to affect the way we are managed and could delay or prevent an acquisition of us on terms that other stockholders may desire.

Furthermore, the interests of Genextra may not always coincide with your interests or the interests of other stockholders, and Genextra may act in a manner that advances its best interests and not necessarily those of other stockholders, including seeking a premium value for its common stock, and might affect the prevailing market price for our common stock. Our board of directors, which consists of nine directors, including one associated with Genextra, has the power to set the number of directors on our board from time to time.

Genextra also may sell share of our common stock into the market from time to time. If we in the future engage in a registered offering of our common stock, we could also determine, as we have done in the past, to register for sale a portion of Genextra's shares as part of that same offering to provide for the orderly sale of such shares. We cannot predict the effect, if any, that future sales by Genextra may have on the market price for our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosure due to error or fraud may occur and not be detected.

You may experience future dilution as a result of future equity offerings or strategic transactions.

In the future, we may issue additional shares of our common stock or other securities convertible into or exchangeable for our common stock in order to raise additional capital or in connection with strategic transactions, including potential in-licenses or acquisitions of products, technologies or businesses. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share you paid for our shares. If we issue securities in connection with a strategic transaction, we cannot assure you that the value of the assets we receive will be commensurate with the value of the securities we may issue, Investors purchasing or otherwise acquiring shares or other securities from us in the future could have rights, preferences or privileges senior to those of existing stockholders and you may experience dilution. You may also incur additional dilution upon the exercise of any outstanding stock options or vesting of restricted stock units or awards.

If securities or industry analysts cease publishing research or reports about us, our business or our market, or if they publish inaccurate or unfavorable reports about our stock, the price of our stock and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about our company. We do not have any control over these analysts, and there can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of the analysts covering us fail to regularly publish reports on us, demand for our common stock could decline, which could cause our stock price and trading volume to decline.

Anti-takeover provisions in our restated certificate of incorporation and our restated bylaws, as well as provisions of Delaware law, might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our restated certificate of incorporation and restated bylaws, as well as provisions of Delaware law, contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Our corporate governance documents include provisions:

- authorizing the issuance of “blank check” convertible preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders, to the extent that no stockholder, together with its affiliates, holds more than 50% of our voting stock;

- eliminating the ability of stockholders to call a special meeting of stockholders;

- permitting our board of directors to accelerate the vesting of outstanding equity awards upon certain transactions that result in a change of control; and

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, as a Delaware corporation, we are subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation Law, or DGCL, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock. Any provision of our restated certificate of incorporation or restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

The existence of the foregoing provisions and anti-takeover measures may also frustrate or prevent any attempts by our stockholders to replace or remove our current management or members of our board of directors and could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful stockholder claims against us and may reduce the amount of money available to us.

As permitted by Section 102(b)(7) of the DGCL, our restated certificate of incorporation limits the liability of our directors to the fullest extent permitted by law. In addition, as permitted by Section 145 of the DGCL, our restated certificate of incorporation and restated bylaws provide that we shall indemnify, to the fullest extent authorized by the DGCL, each person who is involved in any litigation or other proceeding because such person is or was a director or officer of our company or is or was serving as an officer or director of another entity at our request, against all expense, loss or liability reasonably incurred or suffered in connection therewith. Our restated certificate of incorporation provides that the right to indemnification includes the right to be paid expenses incurred in defending any proceeding in advance of its final disposition, provided, however, that such advance payment will only be made upon delivery to us of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification. If we do not pay a proper claim for indemnification in full within 60 days after we receive a written claim for such indemnification, except in the case of a claim for an advancement of expenses, in which case such period is 20 days, our restated certificate of incorporation and our restated bylaws authorize the claimant to bring an action against us and prescribe what constitutes a defense to such action.

Section 145 of the DGCL permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

The rights conferred in the restated certificate of incorporation and the restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons. We have entered into indemnification agreements with each of our officers and directors.

The above limitations on liability and our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their fiduciary duty as directors by shifting the burden of such losses and expenses to us. Although we have increased the coverage under our directors' and officers' liability insurance, certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded. As a result, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to stockholders who may choose to bring a claim against our company.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2016, we had net operating loss carryforwards, or NOLs, for U.S. Federal income tax purposes of $562.3 million, which expire between 2024 and 2036. We also have certain state and foreign NOLs in varying amounts depending on the different state and foreign tax laws.

Our ability to utilize our NOLs may be limited under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, or similar rules. The Section 382 limitations apply if an "ownership change" occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). We have evaluated whether one or more ownership changes under Section 382 have occurred since our inception and have determined that there have been at least two such changes. Although we believe that these ownership changes have not resulted in material limitations on our ability to use these NOLs, our ability to utilize these NOLs may be limited due to future ownership changes or for other reasons. Additionally, tax laws limit the time during which NOLs and certain other tax attributes may be utilized against future taxes. As a result, we may not be able to take full advantage of our carryforwards for U.S. federal, state, and foreign tax purposes.

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 six months ended June 30, 2017 that were not registered under the Securities Act of 1933, as amended, or the 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 June 30, 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: August 3, 2017	By:	/s/ Mark Pruzanski
		Mark Pruzanski, M.D. President and Chief Executive Officer (Principal Executive Officer)
Date: August 3, 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 David Ford, effective as of April 14, 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 June 30, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheet at June 30, 2017 (unaudited) and December 31, 2016 (audited), (ii) Condensed Consolidated Statements of Operations for the three and six month periods ended June 30, 2017 and 2016 (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Loss for the three and six month periods ended June 30, 2017 and 2016, (iv) Condensed Consolidated Statements of Cash Flows for the six month periods ended June 30, 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 April 14, 2017, is entered into by Intercept Pharmaceuticals, Inc. (the "Company") and David Ford ("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 May 8, 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 Human Resources 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.

3. Compensation and Benefits.

3.1 Salary. The Company shall pay Executive an initial annualized base salary of $380,000.00, 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 based on a target 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 12,000 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 6,000 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 Human Resources 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^{th}) 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 Penciling. 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 Pruzanski

Name: Mark E. Pruzanski, MD

Title: President and Chief Executive Officer

Date: April 13, 2017

EXECUTIVE:

By: /s/ David Ford

Name: David Ford

Date: April 13, 2017

Address for Notice Purposes:

[Last address in books and records of the Company]

Exhibit A

RELEASE OF CLAIMS[1]

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 April 14, 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.

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.

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.

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.

<u>Validity</u> – 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^{th}) 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:	______________________ David Ford	______________________ Date signed

Exhibit 31.1

CERTIFICATIONS

I, Mark Pruzanski, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 3, 2017	By:	/s/ Mark Pruzanski
		Mark Pruzanski, M.D. President and Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Sandip Kapadia, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 3, 2017

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Intercept Pharmaceuticals, Inc. (the “Company”) for the period ended June 30, 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: August 3, 2017	By:	/s/ Mark Pruzanski Mark Pruzanski, M.D. President and Chief Executive Officer (Principal Executive Officer)
Date: August 3, 2017	By:	/s/ Sandip Kapadia Sandip Kapadia Chief Financial Officer (Principal Financial Officer)